THE CODEX: LABELLING OF FOOD DERIVED FROM MODERN BIOTECHNOLOGY

(Spine title: The Codex: Labelling of Food Derived from Modern Biotechnology)
(Thesis format: Monograph)

By
Sowmya Latha Hemanahally Vishwanatha
Graduate Program in Law

A thesis submitted in partial fulfillment of the requirements
for the degree of Master of Laws

The School of Graduate and Postdoctoral Studies
Western University, London, Ontario, Canada

WESTERN UNIVERSITY
SCHOOL OF GRADUATE AND POSTDOCTORAL STUDIES

CERTIFICATE OF EXAMINATION

Supervisor	Examiners
_____ Professor Mark Perry Supervisory Committee _____ Professor Sara Seck	_____ Professor Sara Seck _____ Professor Margaret Ann Wilkinson _____ Professor Pratima Bansal

The thesis by
SOWMYA LATHA HEMANAHALLY VISHWANTHA

Title:
The Codex: Labelling of Foods Derived From Modern Biotechnology

is accepted in partial fulfilment of the
requirements for the degree of
Master of Laws

_____ _____
Date Chair of the Thesis Examination Board

Abstract

The controversy surrounding labelling food derived from modern biotechnology plagued the Codex Alimentarius Commission for nearly two decades. The Codex Alimentarius Commission is a joint commission of the Food and Agricultural Organisation and the World Health Organisation, which are specialised agencies of the United Nations. It was set up in 1963 with a mandate to develop and recommend global food standards that protect consumer health and promote international food trade. In 1993, the Codex Alimentarius Commission took on the task of developing a global standard for labelling food derived from modern biotechnology. With several demands for it to discontinue work and an inability to arrive at a consensus, many questioned whether the Codex Alimentarius Commission would be able to develop a standard for labelling food derived from modern biotechnology. Despite all the uncertainties, the Codex Alimentarius Commission finally adopted the "Compilation of Codex texts relevant to labelling of food derived from modern biotechnology." Amidst widespread publicity that the voice of the consumers had finally been heard, the truth about the exact standards is opaque.

This thesis reviews the "Compilation of Codex texts relevant to labelling of food derived from modern biotechnology" and how the Codex Alimentarius Commission arrived at this recommendation. It identifies the ideological differences that led to a contentious debate for nearly two decades and uncovers the possible implications of the panacea adopted by the Codex Alimentarius Commission in July 2011. With the world being divided on possible effects of production and consumption of foods derived from modern biotechnology, the labelling requirements vary from country to country. The final

Compilation of Codex texts is a set of recommendations that accepts different approaches to labelling. The Compilation of Codex texts comprises of a set of ten guidelines that need to be adopted in national labelling legislation or regulations.

This thesis also focuses and compares the labelling requirements in the European Union and Canada. The voluntary model of labelling adopted in Canada permits corporations to choose whether or not to label and some claim that this is a health and safety concern. In the European Union there are more precise criteria for labelling. As the purpose of the Codex Alimentarius Commission is to promote international food trade, this thesis reviews the impact of the Compilation of Codex Texts on the above two alternative approaches to labelling, and examines whether the Compilation of Codex texts can promote international food trade.

Keywords: Labelling, Genetically Modified Food, Food Derived from Modern Biotechnology, Codex Alimentarius Commission, Mandatory labelling, Voluntary Labelling

Acknowledgement

This thesis would not have been possible without the strong support of my Supervisor Professor Mark Perry. I am grateful to him for his patience and trust in me. I appreciate the long hours he has spent and his Socratic method that helped me learn and express my thoughts effectively.

I am grateful to my second reader Professor Sara Seck for her guidance, constant encouragement and support. Her tips on research strategies were largely instrumental in completing my thesis.

I am grateful to the board of examiners Professor Margaret Ann Wilkinson and Professor Pratima Bansal for their time.

I am grateful for the love and support from my husband Krishna Conjeevaram and my son Parasmai Conjeevaram, I am also grateful to my mom late Dr. Prameela Devi and my dad H.V. Vishwanatha who have imbibed in me the strength to face challenges.

I am thankful to Western Law for providing me with this opportunity and the administrative support staff, for their assistance. I appreciate the extensive support of the librarians and staff at the John and Dotsa Bitove Family Law Library.

I am thankful to my friends and colleagues at the Western Law Graduate Program for their intensive discussions and questions, that helped guide my thesis.

Above all, I am thankful to God almighty who made this possible.

Abbreviations

AB- Appellant Body

CAC- Codex Alimentarius Commission

CCFL- Codex Committee on Food Labelling

CFIA- Canadian Food Inspection Agency

DNA- Deoxyribo Nucleic Acid

DSB- Dispute Settlement Board

DSU- Dispute Settlement Understanding

EC- European Commission

EFSA- European Food Safety Authority

ECJ- European Court of Justice

EU - European Union

FAO- Food and Agricultural Organisation

FDMB- Foods Derived from Modern Biotechnology

GATT- General Agreement on Tariffs and Trade

GM –Genetically Modified

GMO- Genetically Modified Organism

SPS- Agreement on Application of Sanitary and Phytosanitary Measures

TBT-Technical Barriers to Trade Agreement

US- United States of America

WHO- World Health Organisation

WTO- World Trade Organisation

Table of Contents

Chapter 1: Overview

"The labeling of genetically modified foods is an extremely complicated subject-one that falls at the intersection of a complex scientific field and deeply held religious, moral, and personal beliefs about what one puts into one's body. It is possible that there is no right answer to the question whether foods should be labeled to indicate genetic modification."

Valery Federici[1]

1.1 Background

Biotechnology is a powerful tool that has developed smart solutions to eradicate several production problems in the food and agriculture industry. It has the potential to help achieve sustainable development of agriculture to meet the need of an expanding and increasingly urbanized population. Although biotechnology has been well accepted in some realms (for example, medicine), its use in the development of genetically modified (GM) food has been at the centre of an extensive and emotionally charged debate.[2] Some of the benefits of use of biotechnology in agriculture include a reduction in pesticide use, increased resistance to various fungal and bacterial infections, the ability to grow crops in drought-prone and high metal-pollution areas, increased yield that has resulted in a reduction of costs, and the production of vitamin- and iron-enriched food.

---

[1] Valery Federici, "Genetically Modified Food And Informed Consumer Choice Comparing U.S. and E.U. Labeling law", online: (2010) 35 Brook. J. Int'l L. at 515 <http://heinonline.org>

[2] FAO Statement on Biotechnology, March 2000, online: The Food and Agricultural Organisation <www.fao.org/biotech/fao-statement-on-biotechnology/en/>

Many, however, are skeptical about the benefits and are concerned with the long-term effects of consuming GM food. There are concerns regarding the environmental effects, such as the impact on bio-diversity, the creation of pesticide-resistant super weeds,[3] and the like that could arise due to extensive growth of genetically modified crops. Although commercial use of genetically modified organisms has been around for some time, the controversy of its use in food production still persists.

Labelling food derived from modern biotechnology (FDMB) has been promulgated as a solution to address the concerns of consumers. Legislation on food labelling aims to provide accurate information to consumers. Labels have to be truthful and should not mislead consumers. The presence of GM ingredients cannot be identified without laboratory testing, and hence the labelling of GM food has been suggested as a way to bridge the knowledge gap between producers and consumers and increase consumer awareness.

The globalization of the food industry has forced the debate over the use of biotechnology beyond national frontiers. The Codex Alimentarius Commission (CAC) is a joint commission of the World Health Organization (WHO) and the Food and Agricultural Organization (FAO), both United Nations Specialized Agencies. CAC has been tasked with establishing health and safety standards and regulating international food trade. The ideological differences among policy makers in different countries have resulted in a wide

[3] Supra note 1 at 525

and confusing spectrum of requirements for the use of modern biotechnology in production and sale of food. CAC has been striving to establish a uniform set of guidelines for almost two decades. On July 5, 2011, a compromise among the policy makers was reached and a "Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology"[4] (Compilation) was adopted.

This thesis traces the negotiations at CAC and reviews the Compilation. An impact analysis is undertaken to examine the possible implications of the Compilation in reducing tensions and promoting free and fair food trade among countries with different models of labelling.

1.2 Research Design

This thesis involves a doctrinal method of research in which a qualitative analysis of both primary and secondary sources of information is undertaken to study the issues surrounding the labelling of FDMB. This thesis is presented in this order: Chapter 1 provides an overview of the thesis; Chapter 2 is an introduction to the thesis topic; Chapter 3 deals with CAC and the controversy over labelling of FDMB; Chapter 4 studies possible impact of the Compilation on future requests for conciliation at WTO. Chapter 5 reviews and compares labelling regulation in Canada to the labelling legislation in the European Union (EU) ; and Chapter 6 presents a summary of the issues arising from this study of the Compilation.

---

[4] Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology, 2011, CAC/GL76-2011, online: Codex Alimentarius Commission < http://www.codexalimentarius.org/standards/list-of-standards/en/>

The details of the methodology adopted in this study vary depending on the chapter being reviewed; however, an overview of the methodologies adopted herein is as follows:

Doctrinal: The first step in this research involved a review and analysis of primary sources such as statues and guidelines both at the national and international level. The secondary materials reviewed include journal articles and books to trace the history of biotechnology as a science, the definition of concepts such as genetically modified organism (GMO) and GM food, the purpose of food labelling, models of labelling legislation in different countries, and issues in its implementation. Subsequently, my research involved a review of the agendas and reports of the meetings of the Codex Committee on Food Labelling (CCFL) related to the labelling of genetically modified food. Such research was primarily undertaken to determine the nature of the labelling controversy at the CAC and to understand the ideological differences amongst countries.

Descriptive: The research involves a descriptive analysis of the Compilation, Canada's labelling policies, and the labelling legislation in the European Union and its implementation in England to determine the exact rules applicable to labelling in the international and national context. Primary materials include (a) the EU Food and Feed Regulation 1829/2003,[5] which creates a harmonized procedure for the scientific assessment and authorization of genetically modified food and feed products, and (b) the

[5] Regulation EC, Commission Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed [2003] OJ, L 268/1 at 13.

EU Traceability and Labelling regulation 1830/2003,[6] which sets out the requirements for a document audit trail to account for and identify approved GM products throughout the marketing chain.. The labelling legislations in England are (a) Genetically Modified Food (England) Regulations 2004,[7] (b) the Genetically Modified Animal Feed (England) Regulations 2004,[8] and (c) the Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004.[9] Labelling legislation in Canada includes (a) the Food and Drug Act[10] and its Regulations, (b) the Consumer Packaging and Labelling Act[11] and Regulations, and (c) "Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering."[12]

Some of the secondary sources reviewed to support my descriptive analysis for this thesis are Genetically Modified Organisms: Why we need transparent system of regulation (Mark Perry, 2010), Genetically Modified Food And Informed Consumer Choice Comparing U.S. and E.U. Labeling law (Valery Federici, 2010), Labeling of genetically modified foods: Legal and scientific issues (Goldman, Karen A, 2000), Regulating biotechnology: comparing EU and US approaches (Patterson, Lee Ann & Josling, Tim, 2002), Labelling Genetically Modified food The Philosophical and Legal Debate, (Paul Weirich, ed. Oxford University Press, 2007), Genetically Modified Food Labelling

---

[6] Regulation EC, Commission Regulation (EC) 1830/2003 of 22 September 2003 on Traceability and labelling of genetically modified organism [2003] OJ, L 268/24
[7] Genetically Modified Food (England) Regulations, SI , 2004/2355
[8] Genetically Modified Animal Feed (England) Regulations, SI, 2004/2334
[9] Genetically Modified Organisms (Traceability and Labelling) (England) Regulations, SI, 2004/2412
[10] Canada Food and Drugs Act, R.S.C. 1985, c.F-27, s 5 (1) and s 5.(2)
[11] Consumer Packaging and Labelling Act, R.S.C. 1985, c.C-38,s 10
[12]Canada, Canadian General Standards Board , National Standard of Canada on Voluntary Labelling And Advertising of Foods That Are and Are Not Products of Genetic Engineering, (Canadian General Standards Board 2004), <http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/norms-standards>

Controversy: Ideological and Epistemic Crossovers (Mikael Klintman, 2002) and A Survey of National Labelling Policies for GM Foods (Peter W.B. Phillips & Heather McNeill, 2000).

Comparative: Subsequent to a review of the above policies and legislations, this research focused on a comparison of the above policies and legislations. Such a comparison provides a basis to understand and highlight possible areas of conflict. This analysis is performed to examine the compliance of labelling policies within the requirements of the Compilation.

Interdisciplinary: The research involves an interdisciplinary study of the impact of international organizations, national legislations, and biotechnology on each other. As the "Codex Alimentarius" or the Food Code is based on scientific analysis, this thesis elaborates the role of science in the standards adopted by Codex. This thesis indicates the relationships between science and international food standards and examines how such food standards are interpreted and adopted by member countries in their national legislation.

Chapter 2: Introduction

2.1 History and Meaning of Biotechnology

The term "biotechnology" was first used by Karl Ereky, a Hungarian engineer in the year 1919. He used the term to refer to a process that produced a product from raw materials with living organisms.[13] However, biotechnology can be traced to prehistoric times, several ancient civilizations realized that microorganisms could be used to make useful products. For example, yeast was used to make beer and wine. Rennet is an example of a natural enzyme mixture from the stomach of calves or other domestic animals that has been used in cheese making for centuries.[14] Thus the use of microorganisms, which forms the basis of biotechnology, is an ancient practice.

Further advances in science revealed that Ereky's definition suggested only one aspect of biotechnology, i.e., the use of a living organism. For many, however, the term "biotechnology" is equated with the manipulation of genes. For a more specific technique of gene manipulation the term "genetic engineering" is considered more appropriate. Genetic engineering dates to the early 1970s. The first experiment to combine different DNA molecules was performed in 1972 in the laboratory of Paul Berg (who shared the 1980 Nobel Prize in chemistry). The following year Stanley Cohen and Herbert Boyer combined some viral DNA and bacterial DNA in a plasmid (which refers to a circular, double-stranded unit of DNA that replicates within a cell. Plasmids are most often found

---

[13] M.G. Fári & U. P. Kralovánszky, "The founding father of biotechnology: Károly (Karl) Ereky", online: (2006) 12:1 Int'l J of Hort'l Sci at 1 < http://www.agroinform.com/files/aktualis/pdf>

[14] Enzymes used in Food Processing (16 August 2010), online: Health Canada <http://www.hc-sc.gc.ca/fn-an/securit/addit/food_enzymes-eng.php>

in bacteria and are used to transfer genes between cells[15]) to create the first recombinant DNA organism.[16] Thus Cohen and Boyer's discovery opened the door for several discoveries in the field of health sciences and agriculture.

Health Canada defines "biotechnology" as a term that covers a "broad range of scientific activities used in many sectors, such as food, health and agriculture." It elaborates further that biotechnology involves the use of living organisms or parts of living organisms for food production and the development of new and innovative products.[17] The usage of the term "living organisms or parts of living organisms" in this definition refers to the process in which the genetic material of a particular living organism is altered by the introduction of genetic material from another living organism. Such genetic material can be derived from plants or animals and be inserted in either species. Sometimes, a bacterium carrying desired traits is introduced into cells to change its genetic material to produce desired consequences. Such a genetically modified plant or animal cell is referred to as a GMO– derived from modern biotechnology.

A GMO according to the WHO is as follows:

> "Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not

---

[15]Medical Dictionary, online: The Free Dictionary, sub verbo "Plasmid" <http://medical-dictionary.thefreedictionary.com/plasmid>

[16] "Paul Berg, Herbert W. Boyer, and Stanley N. Cohen", online, Chemical Heritage foundation <http://www.chemheritage.org/discover/online-resources/chemistry-in-history/themes/pharmaceuticals/preserving-health-with-biotechnology/berg-boyer-cohen.aspx>

[17] "The world has witnessed extraordinary advances in science over the last few decades. Biotechnology - one such area of growth - is a term covering a broad range of scientific activities used in many sectors, such as food, health and agriculture. It involves the use of living organisms or parts of living organisms to provide new methods of production and the making of new products." –Science and Research, Biotechnology (29 July 2008), online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/biotech/index-eng.php>

> occur naturally. The technology is often called "modern biotechnology" or "gene technology," sometimes also "recombinant DNA technology" or "genetic engineering." It allows selected individual genes to be transferred from one organism into another, also between non-related species. Such methods are used to create GM plants – which are then used to grow GM food crops."[18]

Based on the above definitions it can be stated that GMO refers to organisms in which the genetic material or the DNA composition has been altered in order to induce or remove certain traits. This alteration may be achieved through the use of techniques that do not occur naturally. Although genetic modification can be achieved even by conventional breeding techniques, this research focuses on use of modern biotechnology in the production of GM food. Some of the techniques used in modern biotechnology to alter DNA composition, according to Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering is paraphrased as follows[19]:

(a) Recombinant techniques: This involves the use of biological vectors like Plasmids and viruses to carry foreign genes into cells.

(b) Microinjection: This involves injecting genetic material into the recipient cell. This method is used where the cell is large enough, as many plant and animal cells are; the injection can be done with a fine-tipped glass needle.

(c) Electro and Chemical Poration: This involves creating pores or holes in the cell membrane to permit entry of the new genes. This can be done by immersing cells in chemical solutions or by subjecting cells to a weak electric

[18] Food Safety, 20 Questions on Genetically Modified Food, 2011, online: World Health Organisation <http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html>
[19] Supra note 12

current.

(d) Bioballistics: This involves using metals such as gold and silver to deliver genetic material to the interior of the cell. Silver (much smaller than the diameter of the target cell) is coated with genetic material and is loaded on a shotgun to enter the cell. A perforated metal plate stops the shell cartridge, but allows the metal to pass into the living cell. Once in the cell, the genetic material is transported to the nucleus where it is incorporated among the host genes.

2.2 Controversy over the Use of GMO in Food Production

Although GMOs have been used in the production of both food and drugs; it is their use in the production of GM food that has generated extensive debate. Initially, the introduction of the use of GMO in food production was well accepted; however, a controversial study conducted in United Kingdom in the mid 1990s set off a storm. The controversial study highlighted potential harmful effects on the stomach walls of rats due to the consumption of genetically modified potatoes. It was reported in the media in 1996 and was later published in 1999.[20] This led to widespread unrest about the safety of GM food in Europe.[21] The European food scare caused by the mad cow disease, although not directly related to the use of GMO, further compounded the general public's mistrust in

---

[20] Dr. Ewen W.B. Stanley & Pusztai Arpad, "Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine", online: (1999) 354:9187 The Lancet <http://www.thelancet.com/journals/lancet/article/PIIS0140673698058607>

[21] Karen A. Goldman, "Labeling of genetically modified foods: Legal and scientific issues", online: (2000) 12:3 Geo. Int'l Envtl. L. Rev <http://heinonline.org>

science and scientists.[22] This controversy culminated in the passing of the EU's Regulations on GM Food. Despite significant doubts about the validity of the study conducted on rats, suspicion about the safety of FDMB spread across the globe. Several governments, including in the US, re-emphasized the safety of genetically modified food.[23] It was contended that the genetically modified potatoes used in the study were not commercially available and had not been approved for human consumption.[24] Some of the concerns regarding the use of genetically modified organisms relate to their safety in foods, and some to their environmental safety (their impact on biodiversity and the possibility that they might lead to the creation of "super weeds" or insects that are resistant to pesticides).[25]

In addition to the environmental concerns stated above, there are social and psychological concerns that need to be considered. Modern biotechnology has enabled the mixing of genetic material of various species and between the plant and the animal kingdoms. This ability to mix plant and animal genes has raised several religious and ethical concerns and thereby has fuelled the controversy about the use of biotechnology in food production. [26]

Scientists, the food industry, and policy makers in several countries regard the use of biotechnology as the single most powerful tool available in the near future to address the

---

22 Lee Ann Patterson & Tim, Josling "Regulating biotechnology: comparing EU and US approaches", online: (2002) European Policy Papers 8, Archive of European Integration. < http://aei.pitt.edu/28/>
[23] Supra note 21 at 720
24 Supra note 21 at 720
25 Supra note 21 at 719
[26] Supra note 1 at 530

problem of food shortage.[27] The benefits often cited in support of the use of biotechnology in food production are decreased pesticide use, increased yield, and better quality and taste in crops. In addition, a wider variety of crops, the ability to grow drought-resistant crops and increased nutritional value are also cited.[28] Thus there are strong arguments both in favour of and against the use of biotechnology in food production. Concerns about the use of biotechnology in production of food have led to a demand for the labelling of FDMB.[29] Labelling is one of the methods by which consumers can be informed about their food options and therefore choose the type of food they want to consume. Although labelling has been suggested as a solution, it has also contributed to the controversy.

2.3 Labelling of Genetically Modified Food

Food labels provide consumers with information about the product. There are various components to food labels; they describe the nutritional composition of the food, the package size, ingredients, manufacturing information, and the like. Thus these labels provide consumers with information about the product and also impact consumer choice. It is for this reason that governments have an interest in ensuring that the food label serve to help consumers to make their selections wisely.[30] Labels are thus curial to trade and it is because of this that each aspect of a label could generate extensive debate. All countries have packaging and labelling legislation that aim to provide adequate and accurate

---

[27] Supra note 1
[28] Supra note 21 at 719
[29] Supra note 21 at 720
[30] Paul Weirich, ed, Labelling Genetically Modified food The Philosophical and Legal Debate, (Oxford, New York, USA: Oxford University Press, 2007)

information to consumers. Food labels should be truthful and not misleading.[31] The underlying criteria for food labelling is summarized below[32]:

> The primary objective of GM food labelling, and food labelling in general, is to provide truthful information to consumers without misleading them. In addition, food labels are generally designed to serve three purposes:
> (a) to provide adequate and accurate information related to health and safety concerns;
> (b) to protect consumers and industries from fraudulent and deceptive packaging and advertising practices; and
> (c) to promote fair competition and product marketability.

Thus it is necessary for food labels on FDMB to provide adequate and accurate information about this aspect of the product, prevent deception, and at the same time promote fair competition. Even for those who agree on labelling as a possible solution, fulfilling the above three purposes seems to be an insurmountable challenge. Resistance to addressing this challenge may be attributed to the following: a) biotechnology involves the use of complex scientific methodologies, making it difficult to summarize in a simple, clear, and concise label, b) the difficulty of accurately determining genetically modified organism content, c) the perception that product labelling affects product marketability. The labelling of FDMB cannot therefore achieve the same amount of accuracy as other types of labelling and it could obstruct fair trade as they can be misleading.

Some of the arguments against labelling are a) the cost of labelling and misleading labels b) providing insufficient or inconsistent information and c) label verification issues (e.g.,

---

[31] Janice Lee Albert, Labeling of genetically modified foods: Stakeholder perceptions of the food and drug administrations public consultation processes and food industry reactions to the United States voluntary and European Union mandatory policies, (Ph.D. diss., Tufts University Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy, 2007), [unpublished]

[32] Legislative Council Secretariat, Genetically Modified Food Labelling by Diana Wong (Hong Kong: Research & Library Services Division 2003).

negative labelling and the lack of accurate testing to determine claims).[33] Other concerns with labelling are that it is difficult to maintain the traceability of food's origins, and, on a larger scale, that it hampers innovation and scientific advancement. GM foods undergo stringent tests and hence it is surmised that these products do not require additional consumer-directed labelling. Many scientists, stakeholders in the food industry, and policy makers in some countries do not consider it necessary to label GM food. Even though some policy makers appreciate the need to protect the consumer's right to know, they have not been able to implement labelling. The dilemma of policy makers can be summarized thus: "The debate is no longer about whether or not to develop a labelling system for GM foods but rather how to develop a system that provides real consumer choice without unduly interrupting international trade in agri-food products."[34]

2.4 Models of Labelling

The very nature of the problem leads to a dual approach of labelling depending on ideological differences. The two approaches to labelling of genetically modified food are 1) Mandatory Labelling and 2) Voluntary Labelling. It is necessary to understand the benefits and disadvantages of each approach to be able to understand the labelling controversy.

---

[33] Mikael Klintman, "Genetically Modified Food Labelling Controversy: Ideological and Epistemic Crossovers", online: (2002) 32:1 Social Studies of Science at 76 <http://www.jstor.org/stable/3182978>

[34] Peter W.B. Phillips & Heather McNeill, "A Survey of National Labelling Policies for GM Foods", online: (2000) 3:4 AgBioForum < http://www.agbioforum.org>

2.4 (a) Mandatory Labelling

Mandatory Labelling refers to a model of labelling where the legislation of a country requires that products containing genetically modified ingredients be so labelled. In "A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule" the authors state that mandatory labelling "requires food companies (processors, retailers, and sometimes food producers) to display whether the targeted product/ingredient contains or is derived from genetically engineered materials."[35] This definition captures the requirement of labelling for both products and process . It also indicates that food processors, retailers, and food producers are responsible for labelling. This ensures labelling throughout the chain of production and provides for documentation and traceability. This documentation and traceability is essential for verification. The practice of mandatory labelling attempts to bridge the knowledge asymmetry between the producers and consumers. Mandatory labelling legislation around the world varies on certain crucial factors, including "threshold levels," "product or process labelling," and "exceptions to labelling".

Threshold level refers to the maximum amount, expressed as a percentage of intended or unintended genetically modified DNA or protein that is permitted. Anything above the maximum amount would require labelling as containing genetically modified ingredients. For example, the maximum permissible amount of genetically modified content in the EU is 0.9%, in Australia and New Zealand it is 1%, in South Korea it is 3%, and in Japan it is

[35] G.P. Gruer & S.R.Rao, "International Approaches to the Labeling Genetically Modified Foods to Evaluate India's Proposed Rule", online: (2007) 10:1 AgBioForum <http://www.agbioforum.org>

5%.[36] It is important to note that GM ingredients should be approved as safe by the regulatory authorities and only approved genetically modified organisms are permitted to be within the threshold level.[37]

Labelling requirements defined in mandatory labelling legislation vary with respect to their application. Labelling legislation could apply to a product or process. In product-based labelling, the label is required if there are GM ingredients in the final product. In process-based labelling, products that use GMOs during the production process are labelled regardless of whether or GM content is detectable in the end product.[38] China, Brazil, and EU have process-based legislation. Most of the other countries, such as Australia, Japan, and South Korea, have product-based labelling.[39]

Labelling legislation also varies with respect to what is exempt from labelling. For example, in the EU cheese using GM enzymes, milk, eggs, and meat from animals fed with genetically modified animal feed are exempt. In Australia and New Zealand, vegetable oils, food additives, and food processing aids such as enzymes are exempt.[40] The reasons for the exemptions are based on the detection techniques used by governments to enforce labelling laws or in some cases the fact that there are no GM ingredients in the products.

---

[36] Ibid
[37] ECJ, Karl Heinz Bablock and Others v Freistaat Bayern, C-442/09, [2011], EUR-Lex, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62009CJ0442:EN:HTML
[38] Supra note 35 at 59
[39] Supra note 35 at 52
[40] Supra note 35

The advantages of mandatory labelling include the fact that it respects the consumer's right to know; consumers who choose not to consume genetically modified food for personal, religious, or ethical reasons can identify the same and make their informed choice. Mandatory labelling also helps in post-market monitoring for potential unintended effects. Several countries have mandated labelling, and many more are considering adopting the policy. The disadvantages of the mandatory model involve a) a potential increase in commodity prices due to cost of documentation, additional processing and transportation, b) problems accurately tracing food origin, c) difficulty in determining labelling thresholds, d) unfair competition between GM food and conventional food due to the fact that GM food undergoes stringent testing prior to being approved for sale, e) implementation difficulties such as faulty detection techniques, and f) difficulty in communicating appropriate information regarding the use of animal genes in the production of fruits and vegetables.[41] Some other disadvantages include the problem of "misleading labels," i.e., when labels do not provide accurate information, and/or deliberate adjustments to keep genetically modified content below allowed threshold to avoid labelling.

2.4 (b) Voluntary Labelling

Countries that have actively supported the use GMOs in food have adopted a voluntary labelling approach. In some countries, such as the US and Canada, labelling is mandatory only if there is a health or safety issue with a food, for example, the presence of allergens

[41] P. Byrne, "Labeling of Genetically Engineered Foods", online, Colorado State University Extension, <http://www.ext.colostate.edu>

(e.g., proteins from nuts) or some toxins that can raise safety concerns. Although the US and Canada recognize consumer demand for labelling, the belief by policy makers and scientists that genetically modified foods do not differ in any significant way from conventional foods underlies the policy of voluntary labelling.[42] GM food is generally regarded as safe (GRAS). The countries advocating the voluntary approach to labelling claim that GM foods undergo extensive long-term tests before they are approved and are adequately tested to be regarded as safe. The inherent problem of the mandatory model of labels not being able to adequately and accurately inform the consumers about GM content has been cited as a reason for not labelling.

In the voluntary model of labelling, corporations are free to label their products as containing/not containing GM ingredients. This is called positive or negative labelling, respectively. Canada and the US are the largest proponents of the voluntary labelling approach, and have adopted voluntary labelling guidelines. These guidelines aim to achieve consistent and credible labelling systems.[43] Guidelines are important to ensure that the labels are accurate. The low implementation rates with the voluntary labelling approach implies that corporations are not inclined or willing to positively label their product. This may be due to the unfavourable consumer perception regarding genetically modified food, their inability to provide accurate information on labels, documentation costs, and the fact that not all corporations label and so voluntary labelling by some

[42] Supra note 21 at Pg 726
[43] Peter W.B. Phillips & Heather McNeill, "Labeling for GM foods: Theory and practice", online: (2000) 3:4 AgBioForum <http://www.agbioforum.org>

companies could lead to unfair competition.[44] Negative labelling has to be verified, and such labels might not receive approval as almost all crops are modified by plant breeders.[45]

Some of the advantages of voluntary labelling include a) only consumers interested in non-genetically modified food pay the increased cost, b) as genetically modified foods pass extensive safety tests, conducted over several years, there is no need for further labelling, c) providing increased choice to consumer, d) helping to advance biotechnology, e) preventing unfair competition and f) labelling is at the companies' discretion. The disadvantage with a voluntary model is that companies usually choose not to label when provided the choice, hence violating the consumer's moral right to know. It also makes the study of unintended long-term effects difficult and may diminish the market for traditional food products due to a lack of differentiation.[46]

2.5 Underlying Principles for Approval of GM Food

The approval and commercialization of GM food is based on two principles. A country's approach to labelling is also influenced by their application of these two principles.

---

[44] Chris MacDonald & Melissa Whellams, "Corporate Decisions about Labelling Genetically Modified Foods", online: (2007) 75 Journal of Business Ethics at 181 < http://www.jstor.org/stable/25123984>

[45] Peggy G. Lemaux, "Genetically Engineered Plants and Food: A Scientist's Analysis of the Issues (Part1)", online: (2008) 59 Annual Review of Plant Biology at s. 2.3, <http://www.annualreviews.org>

[46] Supra note 44 at 182

2.5 (a) Principle of Substantial Equivalence

The principle of "substantial equivalence" has been recognized by countries despite differences in their approach to labelling. This principle has been adopted in safety assessments for approving GM food for sale and consumption. The Organization for Economic Co-operation and Development (OECD), in its handbook "Safety Evaluation of Foods Derived from Modern Biotechnology" states substantial equivalence as a practical approach to determine the safety of genetically modified food. It can be done by comparing genetically modified food to its analogous conventional food.[47]

The application of the principle of substantial equivalence in the US for the approval of genetically modified food based is summarized below[48]:

> A determination of substantial equivalence requires analysis of GE foods relative to comparable existing foods in terms of protein, fat, starch, amino acid, vitamin, mineral, and phytonutrient composition. GE foods can be designated substantially equivalent to their existing counterparts, substantially equivalent except for certain defined differences (on which safety assessments are then needed), or not substantially equivalent, meaning more safety testing and further review are necessary.

The process indicates that the more different a GM food is, the more elaborate the testing required. In Canada, all applicants must submit an initial application termed "Novel Food Notification," which would contain a complete description of the GM food along with the process of development. Such an application is mandatory to be able to sell or advertise novel foods in Canada. If the information in the application is deemed to be insufficient after a review, then the applicant must submit a "Safety Assessment Data Package,"

---

[47] "Safety Evaluation of Foods Derived from Modern Biotechnology", 1993, online: Organisation for Economic Cooperation and development, <www.oecd.org/dataoecd/37/18/41036698.pdf >
[48] Supra 45 at s. 3.4

which includes detailed information about the safety of use of the product. All safety tests and environmental analysis are undertaken prior to approval.[49] Therefore safety analysis is based on the applicant's disclosure as well as an extensive review by Health Canada.[50] The principle of substantial equivalence is also adopted in the EU to approve GM food. In Canada and the US, subsequent to the approval, corporations are free to choose whether or not to label; whereas, in the EU products containing GM food must be labelled, depending on the threshold limit.

2.5 (b) Precautionary Principle

The Precautionary Principle is also applied by all countries in varying degrees. The aim of the precautionary principle is to protect health and environment from risks.[51] Various interpretations of this principle have led to varied consequences. Cass R. Sunstein[52] details the prevalent interpretations of the "Precautionary Principle" in the international community. According to him, the weakest and most cautious interpretation of the precautionary principle is that "a lack of decisive evidence of harm should not be a ground for refusing to regulate." This implies that if harm can be perceived then governments should be cautious and take preventive measures. Other, stronger, interpretations of the precautionary principle define the extent of damage, who should

---

[49] Guidelines for the Safety Assessment of Novel Foods, Food Directorate Health Products and Food Branch, online: Health Canada<http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/gmf-agm/guidelines-lignesdirectrices-eng.pdf>

[50] Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/gmf-agm/guidelines-lignesdirectrices/index-eng.php>

51 Cass R. Sunstein, "Beyond the Precautionary Principle" The Chicago Working Paper Series, online: (2003) SSRN <http://ssrn.com/abstract_id=307098>

[52] Ibid

bear the burden of proof, and when preventive action should be taken. According to Sunstein, the varied interpretations of the principle have led to a paralyzing effect on development. Excessive interpretations have prevented "all courses of action including inaction," and regulation based on the precautionary principle deprives society of significant "opportunity benefits".[53]

Even though the use of the precautionary principle has been contested as defined above, it has been followed in varying degrees in countries that actively support GM food and in countries where support is not so favourable. The distrust among consumers in Europe has led to the European Commission (EC) interpreting the principle within the context of risk assessment of genetically modified foods and in the management of such risks. Thus, the approval of genetically modified food in the EU requires safety assessment and subsequent labelling based on the precautionary principle. The US, however, has applied the precautionary principle only in assessing risks involved with the use of GM food. Once a food has been assessed as safe then it does not require any further action.[54]

2.6 Codex Alimentarius Commission and Labelling

It was amid these different ideologies and approaches to labelling that the CAC was given the mandate to compile a set of guidelines that deal with the labelling of genetically

[53] Ibid
[54] Diahanna L. Post, "The Precautionary Principle and Risk Assessment in International Food Safety: How the World Trade Organization Influences Standards", online: (2006) 26;5 Risk Analysis <http://onlinelibrary.wiley.com>

modified food. The WHO[55] and the FAO [56] of the United Nations[57] are the two bodies that are responsible for safe and healthy practices and standards at the international level. After almost 18 years of deliberations and discussion, the CCFL finally agreed on a code of text with respect to the labelling of genetically modified food and the Compilation was adopted by the CAC on July 5, 2011. Amid the widespread publicity and media claims about the Compilation, the truth about what exactly was agreed upon by member countries needs to be understood.

In a press release, Consumers International, a global voice for consumers operating in 115 countries, declared a "consumer rights victory" and said

> The Codex Alimentarius Commission has been labouring for two decades to come up with consensus guidance on this topic. …. The new Codex agreement means that any country wishing to adopt GM food labeling will no longer face the threat of a legal challenge from the World Trade Organization (WTO). This is because national measures based on Codex guidance or standards cannot be challenged as a barrier to trade.[58]

National legislations based on the Compilation will not be considered as a restrictive trade practice in a WTO dispute. However, the Compilation recognizes that "each country has the right to adopt its own approach to labelling GM food."[59] Thus, as countries are free to determine their approach to labelling, the issue of a multitude of confusing regulations has not been addressed in its entirety. The next chapter analyzes the problems of determining

---

[55] Constitution of the World Health Organisation, UN TS 1946 No14, online: Yale Law School,<http://avalon.law.yale.edu/20th_century/decad051.asp>

[56] Constitution of the Food and Agricultural Organisation, Can TS 1945 No 32, online: FAO <http://www.fao.org/docrep/x5584e/x5584e00.htm#Contents>

[57] Charter of United Nations, 26 June 1945, Can TS 1945 No 7, online: United Nations<http://www.un.org/en/documents/charter/index.shtml>

[58] Consumers International, News Release, "Consumer Rights Victory as US Ends Opposition to GM Labeling Guidelines", (5 July 2011), <http://www.consumersinternational.org/news-and-media>

[59] Gloria Galloway, "U.S. drops objection to GM food labelling", The Globe and Mail, 6 July, 2011

a standard of labelling at the international level, the role of CAC in addressing the issues of labelling in international food trade and then reviews the Compilation.

Chapter 3: Codex Alimentarius Commission

3.1 Background

The origins of the CAC can be traced back to the beginning of the 20th Century. In 1911, Austria recognized the private notes of experts on the evaluation of food stuff as the "Codex Alimentarius Austriacus."[60] "Codex Alimentarius" is a Latin term meaning "Food Code."[61] The current CAC derived its name from the name of the food standards adopted by the Austro-Hungarian Empire.[62] Subsequently, in 1924, The South American Chemical Congress called for the drafting of the Codex Alimentarius Sudamericanus, which consisted of uniform guiding principles and set model standards for manufactured food.[63] After World War II, there was an increased demand for more international co-operation. In 1958, The European Codex Commission was set up set to effectively promote international co-operation in setting a common "Food Code." The European Codex Commission promoted the idea that the objective of achieving an international food code should be taken under the auspices of the United Nations.[64] In 1960, the Food and Agricultural Organization (FAO) Regional Conference[65] endorsed the need for an international agreement on the minimum food standards.

In 1961, with support of the WHO, United Nations Economic Commission for Europe

---

[60] Richard Wildner, "Codex Alimentarius Commission", online: (1973) 28 Food Drug Cosm. L. J. at 328 <http://heinonline.org/HOL/LandingPage?collection=journals&handle=hein.journals/foodlj28>
[61] Henry I. Miller & Drew L. Kershen, "A label we don't need", Correspondence, Nature Biotechnology (8 November 2011) 971-972 < http://www.nature.com/nbt/journal>
[62] "Understanding The Codex Alimentarius", 3rd Ed. (2006) online: Codex Alimentarius Commission at 6 <ftp://ftp.fao.org/codex/publications/understanding/Understanding_EN.pdf>
[63] Franklin M. Depew, "National and International Food Standards", online: (1964) 19 Food Drug Cosm. L. J. at 492 <http://heinonline.org>
[64] Ibid at 493
[65] Supra note 62

and the Organization for Economic Co-operation and Development and the Council of the Codex Alimentarius Europaeus, the FAO decided to establish the Codex Alimentarius Commission. The FAO requested an early endorsement by the WHO, of a joint FAO/WHO food standards programme. The FAO Conference also proposed that a joint FAO/WHO conference be held in 1962. At the Joint FAO and WHO Food Standards Conference, a proposal endorsing the Joint FAO/WHO Codex Alimentarius Commission to be the principle organ for the joint FAO/WHO Program on Foods Standards was adopted. The Conference also suggested that the first session of the CAC be held in 1963.[66] In 1963, the WHO approved the establishment of the joint FAO/WHO Program on Foods Standards, whose principle organ would be the CAC; it adopted the Statutes of the Codex Alimentarius Commission and agreed to the calling of the first session of the CAC.[67]

One of the preliminary purposes of CAC is the development of the "Codex Alimentarius" or the "Food Code." According to the Ontario Ministry of Food and Agricultural Affairs[68]:

> The Codex Alimentarius represents the world code of food standards. It is an extensive 13-volume compilation of food Standards, Codes of Practice, Guidelines and Recommendations. It is the world's authoritative reference on food standards, and is utilized by national food inspection systems, health authorities, The World Trade Organization, the food industry, scientists and consumer advocates.

---

[66] Sami Shubber, "The Codex Alimentarius Commission under International Law", online: (1972) 21:4The International and Comparative Law Quarterly at 632 < http://www.jstor.org/stable/758119>
[67] Ibid at 633.
[68] Codex Alimentarius and the Codex Commission (7 April 2011), online: Ontario Ministry of Agriculture, Food and Rural Affairs <http://www.omafra.gov.on.ca/english/food/inspection/codex.htm>

Thus Codex Alimentarius consists of a set of standards, codes of practices, guidelines and other recommendations related to characteristics of food products. Some of the texts are general and some are very specific. It could relate to a food or a group of foods, it could also relate to the production and management of the food production process or the operation of government regulatory systems for food safety and consumer protection.[69]

The Statutes and Rules adopted by the FAO in 1961 and by the WHO in 1963, provide the legal basis for CAC. These Statutes state the concepts underlying the work of CAC and the reasons for its establishment. According to Article 1 of the Statutes of the Codex Commission,[70] the purpose of Codex is as follows:

> The Codex Alimentarius Commission shall, subject to Article 5 below, be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:
>
> (a) protecting the health of the consumers and ensuring fair practices in the food trade;
> (b) promoting coordination of all food standards work undertaken by international governmental and non governmental organizations;
> (c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;
> (d) finalizing standards elaborated under (c) above and, after acceptance by governments, publishing them in a Codex Alimentarius either as regional or world wide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;
> (e) amending published standards, after appropriate survey in the light of developments.

---

[69] Supra note 62 at 10
[70] Statutes of the Codex Alimentarius Commission (adopted in 1961 by FAO and in 1963 by WHO), online: Food and Agricultural Organisation Corporate Document Repository <http://www.fao.org/DOCREP/005/Y2200E/Y2200E00.HTM>

The purpose of CAC is to provide international standards to ensure the health and safety of consumers worldwide and to guide member countries to adopt harmonious food standards and thereby promote international food trade. This purpose is also reiterated on the CAC website as follows[71]:

> Codex Alimentarius follows the principle that consumers have a right to expect their food to be safe, of good quality and suitable for consumption. In this regard, the safety and essential quality of internationally traded food is of paramount importance. Codex has set a number of standards and codes on foods for vulnerable groups such as infants and young children, to provide adequate nutrition while protecting them from foodborne risks and to reduce infant mortality and morbidity worldwide.
>
> Codex also aims at protecting consumers against deceptive practices. Codex work in food labelling contributes to providing consumers with accurate and useful information to guide their choice of food.
>
> Codex assists in the harmonisation of national food legislation and regulation of countries which want to use Codex texts as benchmark. International harmonisation of standards facilitates food trade and sustainable economic development. Codex plays an important role particularly for developing countries that may lack the necessary infrastructure and expertise to put in place adequate standards, food safety controls and management systems.

Although the adoption of the CAC's texts is voluntary, many countries choose to adopt these guidelines because policy makers see the benefit to consumers and international food trade. By providing a harmonious standard that could be adopted worldwide, the CAC texts serve a dual purpose of protecting consumer welfare and at the same time promoting international food trade. The CAC texts are based on scientific principles; hence, countries that do not have sufficient infrastructure and expertise consider the CAC texts as valid standards of food safety and control over international food trade. The guidelines/standards established by CAC are of a recommendatory nature and are

---

[71] FAQ's-Purpose of Codex Alimentarius, online: Codex Alimentarius Commission, <http://www.codexalimentarius.net/web/faq_gen.jsp>

not a substitute for national legislation. Countries may adopt these guidelines in their national legislation and make provisions suitable to their specific requirements. This is reiterated in the General Principles of the Codex Alimentarius as follows[72]:

> Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.
>
> Codex standards and related texts contain requirements for food aimed at ensuring for the consumer a safe, wholesome food product free from adulteration, correctly labelled and presented….

Even though CAC standards are optional, most countries do adopt them because the standards/guidelines are based on scientific principles. CAC strives to achieve a consensus prior to the adoption of standards/guidelines/recommendations. Several rounds of negotiations and discussions are held prior to the adoption of the CAC texts, and member countries are given sufficient opportunities to express their concerns. This transparency along with the scientific basis encourages member countries to adopt the CAC texts in their national legislation.

Both the parent organizations (FAO and WHO) act as advisors to CAC. They have convened expert meetings such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA), and ad hoc FAO/WHO expert consultations to advise the CAC as well as member countries. FAO and WHO also provide administrative, managerial, and financial support to the operation

---

[72] General Principles of the Codex Alimentarius, online: FAO Corporate Document Repository http://www.fao.org/DOCREP/005/Y2200E/y2200e05.htm

of the CAC and its committees, in particular those responsibilities assigned to WHO or FAO in the Codex Procedural Manual.[73] The Food and Agriculture Organization is responsible for two-thirds of the funding, with WHO responsible for the other one-third of funds for Codex, however, contributions from FAO have sometimes exceeded 80%.[74]

3.2 Structure of Codex

The CAC meets every year alternatively in Rome and Geneva. The structure of the CAC consists of the Commission, the Executive Committee, and various subsidiary committees that assist in developing food standards.[75] CAC is also supported by its Secretariat. The Commission may be considered as the plenary organ of CAC and it is open to all the members. The Executive Committee, however, is a smaller body with a limited membership, with the overall aim of ensuring a global geographical distribution.[76] Currently, CAC has more than 184 member countries and one member organization (EU). Its sessions are attended by national delegations including representatives from industry, consumer organizations, and academic institutes. Countries that are not yet members sometimes attend in an observer capacity. A number of international governmental organizations and international non-governmental organizations also attend in observer capacity.[77] The countries or participants who attend in observatory capacity can put forward their points of view at every stage except during the final decision. All decisions

---

[73] General Information about Codex Alimentarius, 2012, online: World Health Organisation <http://www.who.int/foodsafety/codex/general_info/en/index3.html>
[74] Eddie Kimbrell, "What is Codex Alimentarius?", online: (2000) 3:4 AgBioForum at 197 <http://www.agbioforum.org/v3n4/v3n4a03-kimbrell.htm>
[75] Supra note 73
[76] Supra note 66 at 633
[77] Supra note 62 at 14

are an exclusive prerogative of member governments.

3.2 (a) Executive Committee

The Executive Committee of Codex comprises the Chairman, three Vice Chairs, and seven elected representatives from the various geographical groups of CAC.[78] Since its formation, the Executive Committee has had representations from more than 45 different countries from all over the world. The Executive Committee acts as the executive organ of the Commission between sessions.[79] The Executive Committee advises Codex and is a smaller group with representations from all the regions[80]:

> The Executive Committee advises the Commission on many questions and serves as a "management board," which would make it impractical to have it attended by 600 delegates (as in the Commission). Instead each region of the world is represented in the Executive Committee through members that have been elected into this position by the membership as well as regional coordinates and the bureau of the Commission. The proceedings and audio recordings of the meetings are later made public.

The Executive Committee advises the Commission on proposals for standards to be developed by a subcommittees of Codex. It also serves as an arm of the Commission and acts on behalf of the Commission in certain circumstances; for example, when the Commission used to meet only once every two years, the Executive Committee could advance steps on standards that were under review by the Commission.[81] The Executive Committee also makes proposals to the Commission related to new work to be undertaken and the study of special problems, and it serves as the standard management body of

---

[78] Supra note 74
[79] Codex Executive Committee (June 2012), online : US Department of Agriculture Food and Inspection Service, <http://www.fsis.usda.gov/codex_alimentarius/Codex_executive_committee/index.asp>
[80] Supra note 71
[81] Supra note 74 at 198

CAC. The Committee generally meets prior to each session of the Commission, and at other times during the year as needed.[82]

3.2 (b) Secretariat

The Secretariat provides administrative support to CAC and is headed by the Secretary. The Secretary is appointed jointly by the Director General of FAO and WHO subsequent to a worldwide search for qualified candidates. The Secretariat is based at the FAO headquarters in Rome. It provides administrative support for both the Commission and the Executive Committee. The Secretariat is responsible for the preparation of the agenda item papers for the meetings, preparation of reports of the meetings, and also necessary follow up activities that are required subsequent to meetings of both Commission and Executive Committee. When the Executive Committee or the Commission decides to develop a new standard, usually the Secretariat drafts a discussion paper detailing what the proposed standard is expected to achieve and a project proposal indicating the time frame for the work and its relative priority. The Secretariat also assists in the preparation of proposed draft standards.[83] The Secretariat is responsible for overseeing, coordinating, and dispersing information about the meetings, agendas, discussion papers, and reports of the subsidiary bodies to the member countries.[84]

---

[82] Supra note 73
[83] Supra note 62 at 15
[84] Supra note 62 at 19

3.2 (c) Subsidiary Bodies

The task of developing CAC standards is carried out is by specific subsidiary bodies. Under the "Rules of Procedure of the Codex Alimentarius Commission"[85], CAC is empowered to establish two kinds of subsidiary bodies: Codex Committees and Co-ordinating Committees.[86] The Codex Committees are further classified into General Subjects Committees and Commodity Committees. The Codex Committees are responsible for the preparation of draft standards for submission to the Commission. The Co-ordinating Committees represent specific regions around the world or a group of countries. They are responsible for co-ordinating food standards activities in the regions they represent. Each Co-ordinating Committee is also responsible for the development of standards specific to the region that it represents.[87]

Each committee, with a few exceptions, is hosted by a member country. The host country is responsible for the cost of the Committee's maintenance and administration and for providing its chairperson. The Commission is responsible for the allocation of the committee to member countries.[88]

The powers of the Commission to establish the above subsidiary bodies have been specified both in its Statutes as well as in its Rules of Procedure. Article 7 of the Statutes

---

[85] "Rules Of Procedure of the Codex Alimentarius Commission", (adopted in 1961) Codex Alimentarius Commission Procedural Mannual, 20th Ed., Codex Alimentarius Commission, http://www.codexalimentarius.org/procedures-strategies/procedural-manual/en/
[86] Supra note 62 at 16
[87] Supra note 73
[88] Supra note 62 at 17

of the Codex Alimentarius Commission[89] states that "The Commission may establish such other subsidiary bodies as it deems necessary for the accomplishment of its task, subject to the availability of the necessary funds." Thus the only precondition, according to this article, that the Commission or the Executive Committee has to consider prior to setting up a subsidiary body is that there should be sufficient funds to enable proper functioning. Rule XI of The Rules of Procedure of the Codex Alimentarius Commission,[90] however elaborates more detailed requirements for establishing the subsidiary bodies. It specifies the different types of subsidiary bodies that CAC can establish, their role, how membership to such subsidiary bodies will be determined, how the chairpersons and coordinators will be appointed, who can convene the sessions of the subsidiary bodies, who determines the place of meetings of these subsidiary bodies, and the funding requirements for functioning of the subsidiary bodies.[91] Rule XI of the Rules of Procedure has been incorporated in this thesis as Appendix II.

According to the Rules of Procedure the conditions necessary for the establishment of a subsidiary body are that, first, CAC must deem it necessary for the development of a standard or the task that it seeks to achieve and, second, there must be sufficient funds to achieve the purpose. Decisions regarding funding requirements are based on the report of the Director General of the FAO and/or WHO as appropriate. Such reports usually detail the administrative and financial implications of establishing a subsidiary body.[92] Thus the availability of funds is an important factor in establishing a subsidiary body, and member

[89] Supra note 70 at article 7
[90] Supra note 85
[91] Supra note 85 at Rule XI
[92] Supra note 85 at Rule IX

countries that are willing to bear the costs of its functioning are allotted a committee.

3.3 Types of Codex Committees

There are two types of Codex Committees, based on the kind of function they perform.

3.3 (a) General Subject Committees

As the name indicates, the functions performed by such committees are of a general significance, i.e., applicable to all food categories. They are also referred to as "horizontal committees." They develop guidelines, standards and concepts that are all-embracing and apply to all foods in general, they endorse or review relevant provisions in CAC commodity standards, and, based on the advice of expert scientific bodies, develop major recommendations pertaining to consumers' health and safety.[93] The committees deal with definitions, rules of procedure, working procedures for the establishment and operation of Codex Committees and Task Forces, relations with other organizations, minimum limits for additives and contaminants, and other similar principles of a general nature with respect to the preparation of CAC standards and codes of practice.[94]

Some of the General Subjects Committees and their roles are summarized below[95]:

> Six of the General Subject Committees have the responsibility of ensuring that specific provisions in CAC commodity standards are in conformity with the Commission's main general standards and guidelines in their particular areas of competence. They are:
> - Committee on Food Additives

[93] Supra note 62 at 17
[94] Supra note 62 at 17
[95] Supra note 62 at 17 and 18

- Committee on Contaminants in Foods
- Committee on Food Hygiene
- Committee on Food Labelling
- Committee on Methods of Analysis and Sampling
- Committee on Nutrition and Foods for Special Dietary Uses

3.3 (b) Commodity Committees

The role of these committees is to develop guidelines and standards that are specific to a particular type of food or class of food. Such committees are also referred to as "vertical committees." These committees meet as and when necessary, sometimes annually or bi-annually. The committees are attended by almost all the member countries and sessions are as large as that of the plenary session of the Commission itself. After completing the work allocated to them, the committees are either suspended or abolished. New committees are established on an ad hoc basis to develop specific standards.[96] It is in such committees that individual countries must express their opinions and concerns prior to the development and adoption of a standard. Once a standard is developed and accepted it is accepted as a world standard, and member countries cannot do much to alter the position later. Hence, there is extensive participation by member countries in these committees. Some examples of commodity committees are Committee on Fats and Oils, Committee on Fish and Fishery Products, Committee on Fresh Fruits and Vegetables, Committee on Milk and Milk Products, and Committee on Processed Fruits and Vegetables, etc.[97]

[96] Supra note 62 at 18
[97] Supra note 62 at 18

3.3 (c) Ad hoc Intergovernmental Task Force

Due to the extensive participation in the committees, the Commission realized that to make sufficient progress they needed a more flexible approach that could help develop standards and guidelines across an ever-widening range of subjects. In 1999, CAC decided to create a third type of subsidiary body called the "Codex ad hoc Intergovernmental Task Force." These committees have very limited terms of reference or are established for a fixed period of time.[98] Since their inception many task forces have been established that have significantly helped to make progress toward the development of new CAC standards and guidelines. In 2000, CAC established the Intergovernmental Task Force on Biotechnology, which has significantly contributed toward the development of four guidelines on risk analysis and food safety of foods derived from biotechnology. These guidelines were incorporated into the final Compilation.

3.3 (d) Coordinating Committees

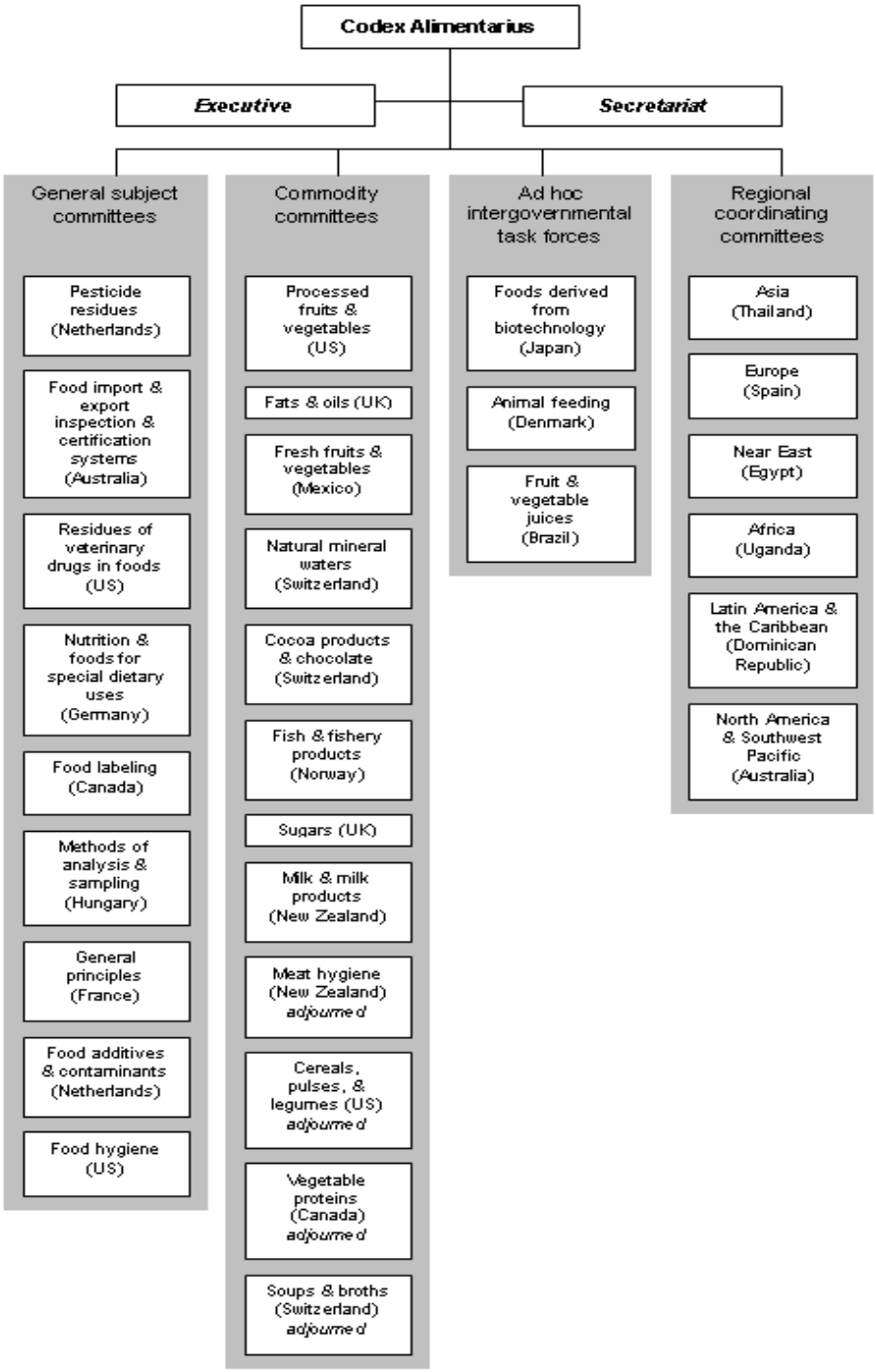
These committees represent the regional interests or group interests of the member countries. They perform an important role in ensuring that the regional or group concerns are addressed, including the concerns of developing countries. There is significant participation in the meetings of the Coordinating Committees. The reports of the meetings of these committees are submitted to and discussed by the Commission. The country that chairs the Coordinating Committee is also the Regional Coordinator for the region.[99] The meetings are usually hosted on a need to basis by one of the members of the region that

[98] Supra note 62 at 18
[99] Supra note 62 at 19

the committee represents, based on discussions with CAC. There are six Coordinating Committees, one each for the following regions: Africa, Asia, Europe, Latin America and the Caribbean, Near East, and North America and the Southwest Pacific.

A tabular representation of the structure of the various committees of the CAC is shown in the figure below

Structure of Codex Alimentarius Commission[100]



[100] Codex Alimentarius Commission Procedural Manual 20th Ed., 2011, online: Codex Alimentarius Commission at 213< www.codexalimentarius.net>

3.4 Procedure adopted for drafting standards at Codex

As stated in Article 1 of the Statutes of the Codex Commission, the primary purpose of Codex is to draft and publish the "Codex Alimentarius" or the "Food Code." The legal principles of Codex are published in The Procedural Manual of the Codex Alimentarius Commission. The procedure for preparing the food code is well defined and transparent.[101] According to the Procedural Manual of the Codex Alimentarius Commission,[102] an initial submission is made either by a national government or a subsidiary body to the CAC or the Executive Committee on the need to develop a standard. Based on this proposal a discussion paper stating the purpose of the standard, the time frame, and the priority is presented to the Commission and/or the Executive Committee for its review. The Commission and the Executive Committee decide on the proposal based on the "Criteria for Establishment of Work Priorities." The Criteria for Establishment of Work Priorities is also detailed in the Procedural Manual of the Codex Commission. The Commission and/or the Executive Committee also decide the subsidiary body that would carry out the necessary work. Sometimes the nature of the work might demand the creation of a new subsidiary body or the revival of a subsidiary body that has been adjourned *sine die.* At other times a specialized task force may be created.

The Secretariat prepares a proposed draft standard and submits the same to the governments of the member countries for their comments. Such comments are reviewed by the subsidiary body that has been allocated the responsibility of developing the

[101] Supra note 62 at 15
[102] Supra note 100

proposed standard. After discussions the subsidiary body may present the amended text as a draft to the Commission. The proposed draft may also be referred to a General Committee – such as the Committee on hygiene, labelling, additives, contaminants, etc. – for specific advice in their respective areas. Subsequent to the recommendations of the Commission and/or the General Committee, the proposed draft is then sent to the governments of member countries for their concerns or comments. The Subsidiary body reconsiders the proposed standard based on concerns raised and, after making necessary modifications as required, resubmits the amended proposed draft to the Commission. After considering the proposed draft the Commission may choose to adopt the text of the proposed draft and included it in the Codex Alimentarius.[103]

The detailed steps for developing a standard at CAC are contained in the "Procedures for Elaboration of Codex Procedures and Related Text," Section II of Procedural Manual[104] and is included in this thesis as Appendix I. A summary of the steps involved is as follows:

- Step 1 the Executive Committee reviews the request for a new standard in the light of criteria and priorities established by CAC and delegates the matter to a particular Codex Committee.
- Step 2 a draft is prepared.
- Step 3 the draft is circulated to member countries and observer participants.
- Step 4 the draft and comments of member countries and observers is reviewed by the Codex Committee and if necessary a new draft is made.

[103] Supra note 62 at 16
[104] Supra note 100 at 31

- Step 5 if the Codex Committee agrees that sufficient progress has been made and there is consensus, it agrees to proceed towards finalisation.
- Step 6 the draft is referred to the General Standards Committee or any other sub committee to check for compliance with other CAC standards.
- Step 7 the draft is reconsidered and finalised based on the suggestions of the committees of CAC.
- Step 8 the draft is referred to the Commission and is adopted by it as a formal Codex text.

An analysis of the steps involved indicates the numerous opportunities for member countries and other participants to express their concerns and points of view. Right from the inception of a proposed draft in Step 1, the committee involved provides opportunity for participants in Step 2, 3, 4 and 5 to express their concerns to the proposed draft. If necessary, a new draft is prepared based on the comments of participants.

Because CAC attempts to develop standards on a consensual basis, the process of developing a new standard usually takes several years. In its Procedural Manual, the Codex Committee in 2003 adopted "Measures to Facilitate Consensus."[105] These measures provide for through discussions and documentation of the issues at meetings, provisions to organize informal meetings to address disagreements and controversies, ways to address all relevant concerns before proceeding to the next steps, and the

[105] "Measures to Facilitate Consensus", (adopted in 2003) Codex Alimentarius Commission Procedural Mannual, 20th Ed., online: Codex Alimentarius Commission <http://www.codexalimentarius.org/procedures-strategies/procedural-manual/en/>

facilitation of increased involvement and participation of developing countries.

Sometimes after the matter has been discussed and sufficient progress has been made at Step 5, a subsidiary body/committee may decide based on the consensus of the members that the proposed draft standard progress directly to Step 8. Such a procedure is termed Step 5/8. Usually only texts that are considered to be ready for final adoption proceed to Step 5/8. The Secretariat will submit the proposed draft standards submitted by the subsidiary body/committee along with comments from member countries for the final review and adoption by the Commission.

Sometimes an accelerated procedure may be adopted by the committee based on a consensus by a two-thirds majority of members of the committee along with subsequent approval by the Commission or by an approval based on a two-thirds majority of members of the Commission. A decision to adopt an accelerated process is based on the outcome of a critical review by the Executive Committee. The method for adoption of an accelerated procedure is also contained in the Procedures for Elaboration of Codex Procedures and Related Text," Section II of Procedural Manual.[106] The procedure is similar to the one described above; however, when the Secretariat circulates the proposed draft to member countries and other observer countries or organizations, they are informed that the matter is being reviewed under the accelerated procedure. Countries and organizations can comment on all aspects, including the impact on economic interests. At Step 5 the matter is sent to the Commission and the Executive Committee along with the

[106] Supra note 100 at 33

comments of member countries and other observer countries and organizations.[107]

Subsequent to the review by the Commission and the Executive Committee, the Commission may decide to adopt the standard and require that the same be published by the Secretariat. Subsequent to its adoption, the Secretariat will publish the same in the Codex Alimentarius and notify all member countries and other international organizations. The member countries and the international organizations notify the Secretariat about the status or the use of the CAC standard as required by the General Principles of the Codex Alimentarius. Paragraphs 4, 5, and 6 state the types of notice that member countries can issue: Countries may accept the CAC standard completely or with certain deviations. The Secretariat is required to publish such notifications as well in the CAC Alimentarius.[108]

3.5 Codex Alimentarius Commission's Standards and Scientific Analysis

The standards, codes, and guidelines developed by CAC are based on sound scientific principles. The scientific issues considered in the CAC documents relate to its two primary purposes: 1) the protection of consumer health through improving quality and safety, and 2) the promotion of fair practices in international food trade.[109] It has been observed that "science, with its proverbial reputation of objectivity, has been identified

---

[107] Supra note 100 at 33
[108] Supra note 100 at 34
[109] Arpad Somogyi, John Hathcock, Hans Konrad Biesalski, Jeffrey B. Blumberg, Jean-Michel Antoine, Gareth Edwards & Peter Prock, "Scientific issues related to Codex Alimentarius goals: A review of principles, with examples", online: (2011) 60 Regulatory Toxicology and Pharmacology at 161 <http://www.ncbi.nlm.nih.gov/pubmed/21382429>

and increasingly implemented in international agreements regulating trade in food, including CAC documents and WTO agreements."[110] The scientific validation of the CAC principles has made it possible for member countries to adopt and apply the CAC standards in their respective national legislation. This in turn has promoted international food trade as sound scientific principles contributed to the removal of non-tariff trade barriers. CAC has delivered standards and guidelines about safety of new technologies. This has also helped developing countries who lack the resources to undertake such analysis. CAC standards have helped to bring about harmonization in requirements in international food trade.[111]

The work of CAC has been supported and validated by several experts and specialists in a wide range of disciplines from all over the world.[112] A review of the CAC's history indicates the role of science in helping CAC guide its work.

> In 1995, the Commission adopted four Statements of Principle Concerning the Role of Science in the Codex Decision- Making Process and the Extent to Which Other Factors are Taken into Account. These principles were supplemented by Statements of Principle Relating to the Role of Food Safety Risk Assessment (1997) and by Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle (2001). A comprehensive statement of Working Principles for Risk Analysis in food safety and health was adopted by the Commission in 2003 and incorporated into the Procedural Manual of the Codex Alimentarius Commission.[113]

The above principles have been adopted based on the fundamental understanding of the CAC paraphrased as follows:

---

110 Ibid at 161
111 Supra note 74 at 199
112 Supra note 62 at 21
113 Supra note 62 at 22

1. Excellence: CAC recognizes and adopts internationally recognized expertise and also generated and global scientific discussions based on best practices.
2. Independence: The scientific advice received and adopted by CAC is from experts who act independently and do not represent the governments of member countries or any institution. Experts are required to declare any possible conflict of interest.
3. Transparency: By adopting the above science-based principles, CAC tries to maintain transparency. All member countries have access to all reports, safety assessments and evaluations, and other necessary information.
4. Universality: As the CAC standards are adopted world wide, the underlying principles have to be universally applicable. It is for this reason that CAC seeks the advice of experts and specialists from all over the world.[114]

The scientific analysis that supports the CAC standards is carried out in the form of collaborative studies among individual scientists, laboratories, universities, and joint FAO/WHO expert committees. The joint expert committees are independent bodies composed of highly skilful and impartial members, whose decisions are indisputably objective.[115] CAC also collaborates with other international organizations such as the International Atomic Energy Agency and World Organization for Animal Health to provide scientific advice to promote food safety.[116] A brief summary of the above scientific principles is stated below to better understand the underlying principles of the Codex Alimentarius.

---

[114] Supra note 62 at 22
[115] Supra note 62 at 23
[116] Supra note 62 at 24.

3.5 (a) Statements of Principle Concerning the Role of Science in the CAC Decision-Making Process and the Extent to Which Other Factors are taken into Account[117]:

The purpose of these statements is to highlight the importance of science in developing CAC recommendations. The first statement in this principle of the role of science states that:

> The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.[118]

The principles require a thorough examination of all relevant scientific evidence prior to the Committee making a recommendation. Requirements contained in these statements include, among others, the following: when conducting a risk analysis for the development of CAC standards, risk assessment and risk management should be separated; all other factors that risk managers propose to take into account should be recorded; and statements indicating how such factors affect risk management options should also be recorded. The principles recognize the "other factors taken into account" on the condition that such other factors should not create unjustified barriers to trade. By adopting a clear scientific basis and transparent approach, these principles promote the two preliminary purposes of CAC, i.e., promotion of consumer health and safety and promotion of fair international food.

---

[117] Supra note 100 at 209
[118] Supra note 100 at 209

3.5 (b) Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[119]

This guideline was adopted by the CAC in 2003 and is intended to provide guidance to CAC and the expert committees in determining the health and safety standards on a scientific and transparent basis. According to this working principle, risk analysis should consist of three components: risk assessment, risk management, and risk communication. The definitions of risk assessment, risk management, and risk communication are as follows:

> Risk Assessment
>
> A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. Risk Management
>
> The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
>
> Risk Communication
>
> The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.[120]

The above definitions indicate the complex nature of study prior to the development of CAC standards and guidelines. The Working Principles require that risk analysis should be based on thorough consultation with all interested parties and that separation should be maintained between risk assessment and risk management in order to assure scientific

[119] Supra note 100 at 105
[120] Supra note 100 at 112

integrity. The Commission provides advice on risk management while the joint FAO/WHO expert bodies and consultations provide advice on risk assessment.[121] The Commission considers all other relevant factors, such as economic implications, societal impact, and the like before developing its report on risk management.

The significance of science in determining the CAC standards, code and guidelines is well accepted by member countries and has helped in promoting international trade.

> Codex member countries have understood from the outset that effective implementation of food legislation requires science-based systems to assure the best consumer protection and to enable clear justification of actions taken to courts, policy makers, and to consumers. It is clear that all matters related to the control of quality or safety of foods, such as net weight, volume, ingredient lists, claims, additives, pesticide or animal drug residues, control of contaminants or food hygiene, must be based on good science.[122]

The transparency with which CAC conducts its risk analysis and the open access it provides to all promotes acceptance and justification of all CAC standards, codes, and guidelines with national policy makers, judiciary, and consumers. Scientifically justified policies promote better harmonization of international food trade policies.

3.6 Codex Committee on Food Labelling

The Codex Committee on Food Labelling (CCFL) was set up in 1964 with a mandate to draft provisions on labelling that would be applicable to all foods, to draft provisions on labelling concerning products given priority by CAC, namely products referred to

---

[121] Supra note 100 at 105&106

[122] John R. Lupien, "The Codex Alimentarius Commission: International Science Based standards, guidelines and recommendations", online: (2000) 3:4 AgBioForum at 194 <http://www.agbioforum.org/v3n4/v3n4a02-lupien.htm>

specific Codex Committees for the elaboration of standards, and to study specific labelling problems assigned to it by the Commission or the Executive Committee.[123] Later the terms of reference were expanded to include a reference to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.[124]

The CCFL is a general committee that is entrusted to draft standards around labelling. Such standards may be general and applicable to all foods, such as the standards that name and provide contents of the products or it could be specific, such as the standards on labelling of "Halal" products. The CCFL also considers, amends, and endorses drafts of specific provisions on labelling prepared by other committees and studies specific labelling problems assigned by the Commission or the Executive Committee.[125]

In 1964, CAC accepted Canada's offer to host the CCFL. Canada is responsible for providing financial and administrative support for the functioning of CCFL, and the CCFL is chaired by a Canadian national. The host country is consulted by the Director General of FAO and WHO before fixing the time and place of the CCFL meeting. The Procedural Manual of the Codex Commission contains the "Guidelines for the conduct of

---

[123] CCFL, 1st Sess, ALINORM 65/22 (1965), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>

[124] Committee Detail of Codex Committee on Food Labelling, 2012, online: Codex Alimentarius Commission<http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList=7>

[125] Codex Committee on Food Labelling (2011), online: United States Department of Agriculture Food safety and Information Services <http://www.fsis.usda.gov/codex_alimentarius/Codex_Committee_Food_Labelling/index.asp>

meetings of Codex Committees and ad hoc intergovernmental task forces."[126] These guidelines regulate and guide host countries on how committee meetings are to be conducted, how standards are to be developed, how reports are to be drafted, and criteria for drafting CAC standards.

3.7 History of development of the Compilation

1. The initial consideration of the proposal to develop labelling standards was in 1993 at the 22nd session of CCFL.[127] The CCFL decided to undertake a study on the Implications of Biotechnology on International Foods Standards and Codes of Practice. It asked governments to provide information on national approaches to labelling of foods and food ingredients or additives produced through biotechnology. The CCFL asked the US to prepare a discussion paper for consideration in the next session.

2. In 1994, at the 23rd session, the CCFL[128] met to review the discussion paper proposed by the US on the implications of biotechnology. The document highlighted developments in biotechnology, previous discussions within CAC with focus on labelling, including enforcement, and the current status of labelling. The paper identified a number of issues for which further elaboration and comments were required, such as the relationship between genetic engineering and conventional

---

[126] Supra note 100 at 90
[127] CCFL, 22nd Sess, ALINORM 93/22 (1993), http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList
[128] CCFL, 23nd Sess, ALINORM 95/22 (1994), http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList

breeding techniques, scientific safety evaluation of substances obtained through recombinant DNA techniques, the use of marker genes, allergenicity, and ethical considerations.[129]

Several countries expressed concerns about the lack of time to sufficiently review the document. Some delegations expressed the view that it was too early to decide on particular rules for products obtained through biotechnology, and that labelling was necessary when the food or ingredient was significantly different from its conventional counterpart, or if safety concerns were involved. Other countries stressed the necessity for full information, as new technologies could benefit the consumers as well as the industry, and transparency in such instances could only help build confidence between the industry and the consumer. The Delegations of Indonesia and Romania suggested that the term "genetically engineered foods" should be used throughout the discussion instead of "biotechnology," as biotechnology covered a broad spectrum of processes and disciplines.[130]

Some countries, such as the US, were of the view that foods derived from the use of genetic modification should be determined safe for consumers and meet the same high standards as foods made by other techniques, labelling should be determined on a case-by-case basis only when a real modification in the composition of the food had taken place, and no general labelling requirement for all foods derived from the use of genetic modification techniques should be made. They also held that all

[129] Ibid
[130] Ibid

decisions should be based on science.

However, some other countries and consumer organizations were in favour of mandatory labelling for foods obtained through biotechnology, as this would enable consumers to make an informed choice. Further concerns about the impact on biodiversity were raised by observer non-governmental organizations. Hence, CCFL felt the need for more elaborate discussions and comments to the discussion paper and decided to adjourn the matter to next session.

A review of this report indicates that the differences in the ideologies to labelling were noticeable right from the inception. The use of the term "modern biotechnology" in the present draft compilation could be attributable to the concerns raised in this meeting of the CCFL. The differences expressed in this session on whether to label GM food and food additives could not be resolved until the very end.

3. In 1996, at the 24th session,[131] the differences became more entrenched. Participants were divided, with some demanding compulsory labelling of all food derived from biotechnology, while others felt that labelling should be adopted on a case-by-case basis. As the CCFL experienced a deadlock, it decided to refer the matter to the Executive Committee for guidance on how to resolve these differences and also on how to implement the four "Statements of Principle concerning the role of science in

[131] CCFL, 24th Sess, ALINORM 97/22 (1996), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>

the CAC decision-making process and the extent to which other factors are taken into account".[132] It also recommended that the Secretariat take responsibility of writing the "draft standards." In the meantime, the FAO and the WHO had set up a joint expert commission to study the safety aspects of food derived from biotechnology. The CCFL suggested that the Secretariat should consider the report and recommendations of the expert commission as well.[133]

In 1996, several countries were still in the process of developing national standards, which was mentioned by the EU and Canada and acknowledged by the CCFL. Because countries had not yet finalized their national policies there was firm divide in the drafting of labelling standards and progress could not be made. The referral to the expert committees was in pursuance to the CAC's commitment to base its standards on sound scientific principles and to ensure the health and safety of consumers.

4. In 1997, in the 25th session,[134] the CCFL had not received a draft from the Secretariat, as several member countries had not provided their comments to the draft proposed by the Secretariat. The Secretariat also suggested that the recommendations had been presented in the form of an amendment to the "General Labelling Standard, following the approach taken for similar issues, and presented the conclusions of the Expert Consultation of particular relevance where labelling

---

[132] Supra note 100 at 209
[133] Supra note 131
[134] CCFL, 25th Sess, ALINORM 97/22A (1997), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>

was concerned."[135] The EC and some other countries approved the same in light of the recommendations of the Joint Expert Committees of the FAO and WHO. Some member countries expressed the view that the draft focused on food safety rather than food labelling and hence needed to be redrafted. The need to use "modern biotechnology" to differentiate from conventional breeding was reiterated. As many countries reiterated the need for more time due to the implications both to consumers and industry, it was agreed to adjourn the matter to the next session.[136]

5. In 1998 at the 26th Session[137], the CCFL introduced the draft prepared by the Secretariat that was modified based on member's comments, called the "Draft Recommendations for the Labelling of Food Obtained through Biotechnology." Some countries and the EC were in favour of labelling "all foods containing GMOs and of foods produced from GMOs but not containing them when no longer equivalent to existing foods or ingredients."[138] They were of the opinion that this would ensure transparency and address consumer concerns. This was, however, not acceptable to certain non-governmental organizations such as Consumer International and the International Federations of the Organic Agricultural Movements or to some countries, such as Norway and India. The demand for the use of "modern biotechnology" was reiterated and was accepted by the CCFL at this session. The CCFL also decided to amend the definitions and to re-circulate the

---

[135] Ibid
[136] Ibid
[137] CCFL, 26th Sess, ALINORM 99/22 (1998), http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList
[138] Ibid

amended draft for comments. Thus, the proposed draft did not move beyond Step 3, although progress was made in the proposal of mandatory labelling in the presence of allergens such as milk proteins. If labelling was not possible then it should not be marketed. The section proceeded to Step 5.[139]

A review of the report indicates the complexity in arriving at a consensual decision. This session also marks the beginning of the manner in which CCFL proceeded with acceptable provisions, which finally contributed to the adoption of the Compilation. The discussions in this session indicate the ideologies of different countries – some countries of the EU and India favoured mandatory labelling, whereas, Canada, the US, Brazil, and Australia supported labelling on safety, composition, intended uses, and nutrition.[140]

6. In 1999, the 27th session of the CCFL[141] reconvened to consider the comments to the Draft Recommendations for the Labelling of Food Obtained through Biotechnology. This session saw more extensive participation and further crystallization in terms of support of the mandatory labelling versus those who advocated labelling only if there was a change in composition, use or nutritional quality. Further, there was more extensive participation for non-governmental organizations. The extensive debate indicated a lack of consensus, and hence CCFL established an Ad Hoc

---

[139] Ibid
[140] Anne. A. Mackenzie "The Codex Alimentarius And Labeling Of GM Foods",online: (2000) 3:4 AgBioForum at 205 <http://www.agbioforum.org/v3n4/v3n4a04-mackenzie.htm>
[141] CCFL, 27th Sess, ALINORM 99/22A (1999), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>

Working Group to consider the definition of biotechnology-derived foods and to establish the two labelling options to be considered by the CCFL later.

The first option would require the labelling of products when they are obtained through biotechnology and differ significantly from the corresponding food with regard to composition, nutritional value, or intended use. The second option involved mandatory labelling based on the method of production. The Working Group was also to look into the establishment of a threshold level in food or in food ingredients for the presence of food or food ingredients obtained through modern biotechnology, below which labelling would not be required. They were tasked also with the establishment of a minimum threshold level for "adventitious" or accidental inclusion in food or food ingredients, of food or food ingredients obtained through biotechnology.[142]

7. In 2000, at the 28th session of the CCFL[143], the Working Group submitted its report. US and some other countries raised new concerns: they stressed the need to address all the implications of labelling foods derived from biotechnology with respect to enforcement, methodology, economic cost, and consumer perception, and proposed that the CCFL, with the assistance of the Working Group, should consider these aspects carefully before taking a decision on mandatory labelling provisions. It was also pointed out that developing countries would face technical difficulties in

[142] Supra note 140 at 205 & 206
[143] CCFL, 28th Sess, ALINORM 01/22 (2000), http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList

implementing provisions for the labelling of foods derived from biotechnology.[144]

There was also further discussion on the use of the term "modern biotechnology." The CCFL agreed to replace the words "food and food ingredients obtained through modern biotechnology" with the words "food and food ingredients obtained through certain techniques of genetic modification/ genetic engineering" throughout Section 2 and in the Title. The use of the term genetic modification or genetic engineering was first suggested by Consumer Rights International, when the CCFL decided to use the term modern biotechnology instead of biotechnology at the 26th session.

The CCFL recognized the diversity in opinions among the member countries and decided to refer the matter for further consideration by the Working Group in light of the new concerns raised by US and other supporting countries. It was also decided that the threshold limits identified by the Working Group should be recommended to the Codex Committee on Method of Analysis and Sampling to review the analytical method of determining the threshold. Thus, the matter did not proceed to the next step and was sent for reconsideration.

The global discussions on the safety of food derived from biotechnology due to the controversial studies in Europe about the safety of genetically modified food led to the Commission setting up an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. The terms of reference to the intergovernmental

[144] Ibid

taskforce were:

- To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology;
- To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as related to foods derived from biotechnology; and
- To take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.[145]

This intergovernmental taskforce undertook to work on the Draft Principles for Risk Analysis of Foods Derived From Modern Biotechnology, and the Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant–DNA Plant. The significance to determine the safety of foods derived from biotechnology led to its final inclusion in the Compilation.

8. In 2001, at the 29th session[146], differences continued and no progress could be made. Argentina requested that no further work be undertaken on this project. They expressed the view that labelling based on process might lead to an impression among consumers that the food was not safe and that this was against the "Statement on Principles on the Role of Science and the Extent to which Other Factors are taken into Account".[147] Therefore, they did not wish to pursue a labelling standard based on the process of production. Some countries also questioned the development of

---

145 First session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, March 2000, online: World Health Organisation <http://www.who.int/foodsafety/publications/biotech/ctf_march2000/en/index.html>

146 CCFL, 29th Sess, ALINORM 01/22A (2001), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList

147 Supra note 100 at 209

guidelines that would provide different options according to the regulatory approach taken in member countries, since this was not the usual approach in CAC and it was not clear how this would apply in case of trade disputes. These delegations indicated that CAC should rather give general recommendations that could be applied in all countries as a basis for international harmonization. The problem of "verification" was also raised in this session, and a suggestion was made that only information that could be varied should be labelled. Italy suggested the idea that labelling should be throughout the food chain and not just at the point of consumption.[148]

It should be noted that these reservations for alternative methods of labelling were made in 2001, and despite this, the adopted Compilation does state that countries are free to adopt a labelling strategy suitable to its requirements.

The CCFL moved a compromised section on definitions to Step 8 for adoption by the Commission by including that "the definitions in the current text were retained and clarified and the definition of 'modern biotechnology' was added, in order to take into account the different approaches taken by member countries as regards the definitions under consideration in the CCFL."[149] The concerns raised with respect to the alternative labelling options complicated the matters further, and the matter was referred back to the working group for reconsideration and for comments from participants.

---

[148] Supra note 146
[149] Supra note 146

9. In 2002, at the 30th session of the CCFL[150], the committee had to reconsider the section on definitions, as the Commission had referred it back to Step 6 for reconsideration due to the lack of consensus. The definition of the term "modern biotechnology" was again discussed with not much progress being made. The CCFL noted that the term "modern biotechnology" was being used in the proposed draft of the Ad Hoc Intergovernmental Taskforce on Foods derived from biotechnology. Many countries were of the opinion that a similar definition should be incorporated to maintain consistency. However, several others were concerned about the use of term modern biotechnology as they felt consumers would not understand the same. Spain suggested that a footnote be included that stated that the use of the term modern biotechnology would not be applicable to the language used in labels. Though some countries accepted Spain's position, there was no consensus and the matter was referred to the work group.[151]

Deliberations with respect to the labelling options also could not move further as new concerns were raised and old concerns were crystallized. The use of the term "genetic engineering or genetic modification" in the title was sought to be replaced with modern biotechnology and this was opposed. Labelling of food based on the process of production was opposed by several countries, including US, Argentina, and Brazil. Canada and a few other countries suggested that voluntary labelling could be included for products that were not different from their conventional

---

[150] CCFL, 30th Sess, ALINORM 03/22 (2002), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>
[151] Ibid

counterparts. This was not acceptable to some members. The determination of threshold was also disputed, with some countries stating that there should be no threshold while others stating that there should be provisions of adventitious inclusion in the production process. With respect to the provisions of exemptions, some members were of the opinion that some products could be excluded while others felt that there should be no exemptions. Finally, with respect to the labelling declarations some countries stressed the need for verification methods, while others felt this matter needed further discussions.[152]

CCFL recognized that no consensus could be reached on several important sections and thereby referred the draft recommendations on labelling back to step 3 for further comments.

10. In 2003 at the 31st session,[153] the CCFL recognized the difficulties in coming to a consensual decision. The chair called for establishment of a group called "Friends of the Chair," as an inter-sessional mechanism to break through the difficulty that CCFL was facing. The participants agreed to this proposal on the condition that transparency and balanced geographical representation between developed and developing countries would be maintained. The CCFL decided to adjourn the discussion on draft definitions to Step 7 and the proposed draft guidelines to Step 4 for further discussions in the next session. Thus, nothing significant was achieved in

[152] Ibid
[153] CCFL, 31th Sess, ALINORM 03/22A (2003), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>

this session and much was hoped to be achieved in the smaller group setting that was to be convened subsequent to the CCFL meeting.[154]

11. In 2004 at the 32nd session[155], the CCFL started with the mandate to develop options for the management of this agenda item. The working group "Friends of the Chair" had recommended that work be continued on this item, and considerable interest was expressed in maintaining a single document with mandatory components and other optional provisions. No consensuses could be reached with respect to the exact nature of the components. The working group had also suggested that the matter be referred to the FAO, WHO, and the WTO as the CAC standards had significant implications on a WTO dispute. Some of the concerns raised were the possible impact on food prices in developing countries should labelling be mandated on process and the impact of such labelling on the Agreement on Technical Barriers to Trade.[156] Many countries highlighted concerns that lack of harmonization regarding labelling of foods derived from modern biotechnology could lead to trade barriers in international food trade. As some participants expressed concern on referring the matter to FAO, WHO, and WTO, the committee agreed to return to the proposed draft in the next session. Thus no progress was made on key issues except for highlighting the costs of mandatory labelling.[157]

---

[154] Ibid
[155] CCFL, 32nd Sess, ALINORM 04/27/22 (2004), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>
[156] Agreement on Technical Barriers to Trade, 15 Apr. 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 117, <http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm>
[157] Supra note 155

12. In 2005, at the 33rd session of the CCFL[158], the stalemate continued. Despite the matter being referred back for further comments, no agreement could be reached. Canada suggested that the proposed draft guideline consist of two components, one in which there is mandatory labelling in the case of changes in nutrition content, composition, end use, or presence of allergens; and an optional provision linked to voluntary labelling of the method of production by the industry. Several countries were against adopting labelling based on production because it would result in increased price and lead to inaccurate and misleading labels, and because they were of the opinion that it was against the Statements of principles on the role of science. The committee decided to establish an electronic working group in order to make progress for consideration at the next session. In addition, no progress was made with respect to the deliberations on the definitions section.[159]

13. In 2006, at the 34th session of the CCFL[160], the electronic working group had reconstructed the guidelines, including mandatory provisions for health- and safety-related labelling and the optional method of production-labelling provisions. Many participants expressed their concerns over these amended guidelines, and no progress could be made. Suggestions were made to discontinue work on this agenda as no consensus could be reached. However, some countries expressed that discussions should continue given the importance of this topic to consumers and to

---

[158] CCFL, 33rd Sess, ALINORM 05/28/22 (2005), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>
[159] Ibid
[160] CCFL, 34th Sess, ALINORM 06/29/22 (2006), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>

developing countries, as it would facilitate the establishment of national policies in such countries. The chairperson noted the considerable support to continue work and decided to establish a physical working group to consider all relevant issues and identify main problems. The mandate of the working group was to consider the rationale to the members' approach to labelling, identify current labelling standards, regulations, or policies, identify members' practical experiences in applying and implementing labelling policies, and identify strategies used to communicate to the public about foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how members label these foods.[161] It was also established, with a view to promoting better communication with participants, to arrive at a consensual path. The CCFL agreed to leave matters undecided and reconvene in the next session, based on the recommendation of the working group, that had just been established in this session.

14. In 2007, at the 35th session of the CCFL[162], discussions were primarily based on the safety of GM food. The Inter-governmental Task Force on Foods Derived from Biotechnology stated that several elaborate tests had been adopted by the commission to address risk analysis and safety assessment for foods derived from recombinant DNA, plants, and micro-organisms. Therefore the safety concerns about GM food were sufficiently addressed. Several participants reiterated the need for mandatory labelling to respect the consumers' right to information. Others

[161] Ibid
[162] CCFL, 35th Sess, ALINORM 07/30 /22 (2007), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>

opposed this view stating that the consumers' right was not one of the rights included in CAC's purpose in the Statutes of the Codex Alimentarius Commission. The working group had come up with different approaches to labelling; however, no consensus was reached. The working group had also identified possible options for further action by CCFL but had not considered them in detail due to the lack of time.

Though the working group had made some progress, it was not sufficient, and hence CCFL decided to establish another physical working group between sessions. There was a demand to abandon the work on this item as some thought that no consensus could be reached. However, others reiterated the importance of this work and the CCFL decided to set a timeline for the completion of this task as 2011. The mandate of the working group was to look at the problem with a different perspective. This time the working group was asked to identify the rationale of not adopting a particular approach; it was asked to revisit communication strategies and to review current CAC texts to determine if they provided sufficient guidance. Based on this review they were to determine a way forward. The working group was to base its decision on previous guidelines, discussions held at the CCFL meetings, informative background papers prepared by US , the guidelines of the Executive Committee, the CAC Procedural Manual, and any other relevant CAC texts, WHO, or FAO texts.[163] The matter was adjourned for deliberations in the working group and for a review the next year.

[163] Ibid

15. In 2008, at the 36th session of the CCFL[164], a similar situation continued. The working group failed to reach a consensus. It was suggested that as a consensus could not be reached, a list of principles or concepts to be taken in to account should be detailed instead of developing a standard on labelling. CCFL recognized the large support for this idea and decided to replace the proposed draft guidelines with a set of recommendations. US opposed this move. Consequently, the CCFL decided to refer the matter to Step 3 for comments from participants. The significance of this session is that it opened the doors for the Compilation. The final adopted text is a set of recommendations as suggested in this session.[165]

16. In 2009, at the 37th session of the CCFL,[166] demands were made to discontinue work on this agenda as no progress was being made despite referring the matter to a set of recommendations. However, many countries felt the need to continue as the proposed draft recommendations could prove useful over time. CCFL continued discussion on the proposed recommendations but no consensus could be reached and the matter was withheld at step 3 for further consideration at the next session.[167] Even in 2009, no progress was made on this matter and countries remained divided on product versus process labelling. Even though CCFL agreed to promote the text as a recommendation, nothing changed with respect to the ideologies of participating countries.

---

[164] CCFL, 36th Sess, ALINORM 08/31/22 (2008), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>
[165] Ibid
[166] CCFL, 36th Sess, ALINORM 09/32/22 (2009), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>
[167] Ibid

17. In 2010, the 38th session of the CCFL[168] saw the beginnings of the final adopted Compilation. The discussion primarily focused on the purpose and scope of the recommendations, and much progress was made. The participants agreed that different countries had different approaches to labelling and that the CAC compilations should recognize the same.[169] The deliberations at this session indicated a shift from the earlier stalemates toward an acceptable set of recommendations.

18. In 2011, the 39th session of the CCFL[170] marked the culmination of a long 18-year struggle to develop an acceptable set of guidelines for labelling of food derived from modern biotechnology.[171] The members agreed to an amendment of the title to read "Proposed draft compilation of Codex texts relevant to labelling of food derived from modern biotechnology." Argentina expressed reservations on the adoption of this title; however, the committee accepted it as a working title and decided to revisit it later. It was agreed that the purpose of the recommendation should read, "the purpose of this document is only to recall in a single document some important elements of guidance from Codex texts which are relevant to labelling of foods derived from modern bio-technology." The members agreed that a list of the applicable CAC texts should be made through a hyperlink and there was no

[168] CCFL, 37th Sess, ALINORM 10/33/22 (2010), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>
[169] Ibid
[170] CCFL, 38th Sess, REP11/FL (2011), <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList>
[171] Ibid

requirement to provide detail for each of the applicable provisions. This proposal was accepted to facilitate amendments in future. The delegation also agreed to include the general guidelines for the term halal,[172] and also general guidelines on claims. Many delegates were of the opinion that as no further questions remained the document should be advanced to the commission for adoption at step 5/8 in May 2011.

19. The "Proposed Draft Compilation of Codex Texts Relevant to Labelling of Food Derived from Modern Biotechnology" was finally adopted at the Commission in July 2011 at steps 5/8. The Chair of the CCFL suggested a clarification to the footnote, which provided a definition of "modern biotechnology." This was accepted by the members and the draft was adopted at Step 5/8.[173]

The deliberations reveal the strong standpoints of policy makers around the world with respect to labelling of food derived from modern biotechnology. Despite the several years, the CAC finally adopted a set of recommendations. The concerns about the adoption of alternative options to labelling could not be addressed. Various important sections with respect to threshold and verification were also not addressed. As countries now have the right to decide the model of labelling that suits their needs, it is now up to non-governmental organizations to pursue their demands with respect to the consumer's right to information at the national level. The widespread publicity that the consumer's voice

---

[172] General guidelines for Use of the Term 'Halal',1997,CAC/GL 24/1997, online : Codex Alimentarius Commission <www.codexalimentarius.net/download/standards/352/CXG_024e.pdf>

[173] CAC, 34th Sess., REP11/CAC (2011) <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList=1>

had been heard is not true in its entirety. The truth will vary depending on the national policy.

Because CAC texts are considered as a standard in a WTO dispute, the fact that CAC now accepts opposing models of labelling with variations could be a source of future contention, and despite the length of deliberations, the extent to which the CAC code assists in promoting an international trade decision would probably require a judgement from the WTO.

3.8 Compilation of Codex Texts Relevant to Labelling of Food Derived from Modern Biotechnology:

The 2007 session of the CCFL set a deadline of 2011 for finalizing the draft guidelines on labelling of food derived from genetic engineering. Keeping this deadline in mind, the 2010 session setup a working group, which was largely instrumental in developing the Compilation. The final adopted recommendation is incorporated in this thesis as Appendix III.

The working group that met in Brussels, Belgium, in November 2010 was tasked with exploring the objectives of different delegations with regard to various versions of the texts being circulated, and to reconcile them in one text, if possible.[174] The group focused

[174] Report of the Facilitated Work Session of CCFL 39th session, CX/FL 11/39/13, (2011) <ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl39/fl39_13e.pdf.

on the original purpose of the agenda item as dictated to the CCFL by the Commission, which was to "provide guidance on how the fact that a food was derived from modern biotechnology could be made known to the consumer."[175] The group considered and discussed the views adopted by member countries in order to understand the objectives and the rationale behind the positions adopted. After an extensive preliminary discussion, the working group was further sub-divided into four groups. Each group was asked to develop a statement on the objectives of a labelling text and the key indicators of success that such a text would reflect. A general compilation of the objective of a labelling standard was agreed to as follows:

> Articulate guidance based upon existing Codex texts which can inform member countries national frameworks for the labelling of foods derived through modern biotechnology (FDMB):
> • Providing principles relevant to FDMB within the Codex framework for labelling all foods.
> • Supporting informed choice by consumers
> • Enabling different approaches to the national framework supporting the above[176]

This objective reveals a general understanding among member countries that there are different approaches to labelling and that labelling of food derived from modern biotechnology should be based on prevalent CAC Texts.

Subsequent to establishing the objective, the working group discussed the text that had been circulating among member countries since 2009. This involved a discussion of the title of the document, the purpose, and the text. There was no consensus with respect to the title of the document; however, progress was made with respect to the 'purpose' and

[175] Ibid
[176] Ibid

the 'considerations text' that was included in the options provided for further discussions to the CCFL. The participants concurred that there were three possible approaches to the manner in which the recommendations could be drafted, and their report summarized the options as follows:

> (a) The guidance could make reference to the relevant texts in paragraph 1 of the Appendix with the addition of the Codex Guidelines for the Production, Packaging and Labelling of Organic Foods and the Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals and include reference to particularly pertinent sections.
> (b) The guidance could make reference to the relevant texts found in paragraph 1 (with the addition of the Codex Guidelines for the Production, Packaging and Labelling of Organic Foods and the Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals) and include reproductions of the relevant specific sections in table 1.
> (c) All relevant texts could be reproduced in the guidance document.[177]

Although the three options agreed on the same set of texts to be included, they varied in the method of their incorporation/presentation in the Compilation. The working group suggested the above three options to the 39th session of the CCFL when it met in 2011.

Clarity in the purpose and considerations texts proved to be very useful in the final adoption of the Compilation. The purpose, as indicated in the Compilation, was to combine in a single document all CAC Texts relevant to the labelling of foods derived from modern biotechnology and is based on the consideration that there are different approaches to labelling and that the Compilation does not suggest that FDMB are different from other foods merely due to the method of production. It also reflects the understanding among participating members that any national framework for labelling of

[177] Ibid

FDMB has to be in accordance to the adopted CAC texts.[178]

The first text identified by the Compilation is the "Codex General Standard for Labelling of Prepackaged Food."[179] The text on labelling of FDMB has particularly incorporated sections 3.1, 3.2, 4.1.1, 4.1.2, 4.2.2, and 7.1. This code deals with the labelling requirements for prepackaged food. It requires that labelling should be truthful, not misleading or deceptive; labels should not be confusing or deceptively suggest that the item is connected with another product/producer. The guidelines also contain mandatory labelling provisions, as detailed in section 4.1.1 and 4.1.2[180] that have been incorporated into the Compilation. The mandatory provisions require that unless expressly provided, a label shall contain the name of the food and the true nature of the food. If a CAC Standard has incorporated a specific name, such a name shall be included in the label, otherwise the name as indicated in the national labelling legislation should be specified. Section 4.2.2 contains specific reference to FDMB. This section only refers, however, to allergens transferred in cereals containing gluten, eggs, fish, peanuts, soybeans, milk, tree nuts, and nut products. The section requires that such ingredients be declared and if it is not possible to provide adequate information then such products should not be marketed.[181]

Section 7.1, which deals with optional labelling, states that any information or pictorial device written, printed, or graphic matter may be included in a label provided that it is not

---

[178] Supra note 4
[179] Codex General standard for labelling of Pre-packaged Food, 1985, Codex-Stan 1-1985, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>
[180] Ibid s 4.1.1 & 4.1.2
[181] Ibid s 4.2.2

in conflict with the above requirements. This section could be interpreted as supporting positive or negative labels that indicate the presence or absence of GM ingredients in food. Thus, unless there is the presence of allergens, the Codex General Standard for Labelling of Prepackaged Food does not require FDMB to be labelled, but if they are labelled, then the criteria is that it should be truthful, not misleading or deceptive. This guideline supports either model of labelling provided it meets with the mandatory requirements contained therein.

The second text stated in the Compilation is the "General Guidelines on Claims"[182]:

> a claim is any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.[183]

Thus, according to this definition, any declaration of whether a food contains or does not contain GM ingredients is a claim and must comply with the provisions of this guideline. According to the Compilation the applicable sections of this guideline are sections 1.2, 1.3, 2, 3.3, 3.5, 4.1 and 5.1 (iii), 5.1 (iv), 5.1(v) and 5.1(vi).[184] Section 1 echoes the idea that a label should be truthful and not misleading or deceptive. It requires that a person making a claim should be able to justify the same. Section 3.3 and 3.5 prohibits claims that cannot be substantiated or that give rise to doubt about the safety of similar food or that could arouse or exploit fear in the consumer.[185] Section 4.1 prohibits the use of meaningless claims that involve the use of comparatives and superlatives. Section 5.1 (iii)

---

[182] General Guidelines on Claims, 1979, CAC/GL 1-1979, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>
[183] Ibid
[184] Ibid
[185] Ibid s3.3 and 3.5

to (vi) specify claims that could be used provided they are in compliance with national practices and other guidelines adopted by the CAC. This section also requires that such claims should not be specifically prohibited by prohibited by Section 3.3 and 3.5. Section 5.1(iv) deals with claims pertaining to religious and ritual preparation (both Halal and Kosher) requiring that such claims should confirm to the requirements of the appropriate religious or ritual authorities. Further, it does reference the CAC text on preparation of 'Halal' foods.

The provisions of this guideline that are applicable to labelling of food derived from modern biotechnology provide a basis for using labels, whether positive or negative, on genetically modified food. Labels have to comply with the above restrictions in order to be considered as fair claims according to the CAC texts. Thus, labels on GM food, whether positive or negative, should be truthful, should not create doubts about the safety of similar food, and should not arouse or exploit fear in the consumer about the safety of foods derived from modern biotechnology. Labels should not involve the use of comparatives or superlatives and should not be against other CAC guidelines.

The third guideline that has been incorporated into the Compilation is "Guidelines for the Use of Nutrition and Health Claims."[186] The Compilation requires labelling of foods derived from modern biotechnology to be compliant with national policies on nutrition and health claims supported by sufficient scientific evidence. It also requires that nutrition and health claims should be truthful and based on General Guidelines on Claims as stated

[186] Guidelines for the use of Nutrition and Health Claims, 1997, CAC/GL 23-1997, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>

above. The guideline has a set of recommendations on the scientific substantiation of health claims annexed to it. This annexure elaborates the manner in which scientific studies have to be undertaken and how analysis should be made. Thus any nutrition and health claims of FDMB should be substantiated on a scientific basis, as required by this guideline. The prohibitions as stated in the General Guidelines on Claims are also adopted in the Guidelines for the use of Nutrition and Health Claims.

The fourth text adopted in the Compilation is the "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods."[187] Section 1.5 specifically excludes foods derived from the use of genetic engineering from being certified as organic. This expressed exclusion clearly differentiates certified organic foods from FDMB.

The fifth text adopted is "General Guidelines for Use of the Term 'Halal,'"[188] which was included to accommodate the religious concerns of consumers. The purpose is to provide guidance to producers of FDMB. It lays down the permissible ingredients and the method of production necessary for genetically engineered food to be certified as "Halal."

---

[187] Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, 1999, CAC/GL 32-1999, online : The Codex Alimentarius Commission at s 1.5 <http://www.codexalimentarius.org/standards/list-of-standards/en/>

[188] General Guidelines for Use of the term "Halal", The Codex Alimentraius Commission, 1997, CAC/GL 24-1997; <http://www.codexalimentarius.org/standards/list-of-standards/en/>

The sixth guideline incorporated into the Compilation is the "Principles for Risk Analysis of Foods Safety for Application by Governments."[189] These principles guide member countries on "risk assessment, risk management and risk communication with regard to food related risks to human health."[190] The principles stated in this guideline "apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner."[191] They provide the scientific basis on which member countries can develop and implement the approval and marketing of foods derived from modern biotechnology. Risk analysis is divided into three parts – risk assessment, risk management, and risk communication. This principle requires that all three components be treated as interrelated and be applied in a transparent manner. This principle guides member countries on identification and analysis of certain components of food.

The seventh CAC text in the Compilation is "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology."[192] This guideline elaborates the principles for risk analysis specifically for foods derived from modern biotechnology. It provides guidance on evaluating foods that lack history of use. The definitions of risk assessment, risk management, and risk communication are based on the CAC Guideline on "Working Principles for Risk Analysis for Application in the Framework of the Codex

---

[189] Working Principles for Risk Analysis for Food Safety for Application by Governments, 2007 , CAC/GL 62-2007, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>
[190] Ibid at para 1
[191] Ibid at para 3
[192] Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, 2003, CAC/GL 44-2003, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>

Alimentarius."[193] The risk assessment should be in consultation with the risk management experts and it should involve hazards identification, hazard characterization, exposure assessment and risk characterization. With respect to risk management, the principle states:

> National government decisions on risk management, including sanitary measures taken, should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.

This presents one of the primary grounds on which mandatory labelling legislation could be challenged. Mandatory labelling legislation intended to be used as a risk management policy would be required to establish that its primary objective is the protection of the health of consumers. It should be justified and applied uniformly across similar scenarios. Risk management should also take into account economic consequences and feasibility. All risk analysis should include clear communication among risk assessors, risk managers, and other interested parties. This principle provides a framework for undertaking risk analysis on FDMB. It also provides a definition of biotechnology as stated in the Compilation:

> Modern biotechnology means the application of:
> In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid in to cells or organelles. or Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.[194]

In paragraph 19, which deals with risk management measures, the principle states that risk

---

[193] Supra note 100 at 105
[194] Supra note 192 at para 2

management measures may include, as appropriate, food labelling conditions for marketing approvals and post market monitoring. Paragraph 20 states that post-market monitoring may be justified if there is a need determined on a case-to-case basis. Post-market monitoring may be undertaken for the purpose of "verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects…."[195]

These two paragraphs provide the basis on which member countries could justify their mandatory labelling legislation. Countries are free to label foods derived from modern biotechnology if they intend to observe their impact on the health of consumers. The principle does not state how long such labelling could be adopted as a risk management technique but it provides a basis on which countries intending to adopt a mandatory labelling approach could do so without sanction from the World Trade Organization.

The eighth CAC text incorporated in the Compilation is the "Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant DNA Plants."[196] This principle is intended to address the safety and nutritional aspects of whole foods derived from plants that have been modified by modern biotechnology to exhibit new and altered traits. The safety assessment under this principle is based on the concept of substantial equivalence wherein foods derived from new plants, including plants that have been modified by modern biotechnology, are compared to their conventional counterparts that

---

[195] Supra note 192 at para 20

[196] Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants, 2003, CAC/GL 45-2003, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>

have a history of safe use. All intended and unintended effects of the whole food are considered prior to the commercialization of such foods. The principle requires that attention be given to new altered hazards and supports the post-market monitoring of such hazards. In paragraph 6 this principle specifically mentions "The Principles for Risk Analysis of Foods derived from Modern Biotechnology"[197] that promotes "labelling" as one of the tools for post market monitoring of foods derived from modern biotechnology. The guideline provides a detailed description of the key areas for conducting a risk analysis of the new food, including an annexure on the "Assessment of Possible Allergenicity," that requires the identification of the new protein and the safety assessments prior to commercialization.

The ninth CAC text incorporated in the Compilation is the "Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms."[198] This principle is intended to address safety and nutritional aspects of foods produced through the actions of recombinant-DNA microorganisms. Such recombinant-DNA microorganisms may be present or used in to assist in the productions of foods. This principle is also used along with the "Principles for Risk Analysis of Foods derived from Modern Biotechnology", and in paragraph 7 it also supports labelling as a tool of post-market analysis to monitor the unintended effects of microorganisms.

The last CAC text incorporated in the Compilation is the "Guideline for the Conduct of

---

[197] Supra note 192

[198] Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms, 2003, CAC/GL 46-2003, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>

Food Safety Assessment of Foods Derived from Recombinant-DNA Animals."[199] This principle addresses the safety and nutritional aspects of foods consisting of, or derived from, animals that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits.[200] The principle recommends the approach for food safety assessment for foods derived from recombinant-DNA animals where a conventional counterpart exists. It recommends the use of the best scientific knowledge to ensure that the food does not cause harm when cooked or consumed. The safety assessment is intended to capture the unintended effects of the food that has been modified by the use of modern biotechnology.

Thus the Compilation attempts to integrate all the relevant texts with respect to the approval of food derived from modern biotechnology. Even though these texts existed prior to the Compilation they have been amended to integrate them into the issue of labelling. Though the Compilation does not support one model of labelling over the other, it does provide guidance to member countries who wish to adopt labelling legislation. The scientific basis required for the approval and sale of FDMB along with the restriction that post-market monitoring should be justified to the extent of perceived risk, provides the foundation on which a labelling model should be based.

The Principles for Risk Analysis of Foods derived from Modern Biotechnology, which suggests labelling as a tool for post-market analysis, does not prescribe the duration for

---

[199] Guideline for the conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals, 2008, CAC/GL 68-2008, online: The Codex Alimentarius Commission <http://www.codexalimentarius.org/standards/list-of-standards/en/>

[200] Ibid s 1.1

which labelling would be required. It also does not deal with the kind of information that could be included in such labels. Even though international agreements and guidelines provide for discretion to national legislatures, the exact extent to which labelling could be used as a tool for post-market monitoring should have been addressed by the Compilation. The Compilation does not address several issues raised during the discussions, such as the threshold limit, verification techniques, whether there should be product or process labelling, and what products could be exempt from labelling. The existence of these loose strings could undermine the efforts made by CAC to provide a panacea to the problem of labelling of FDMB.

Chapter 4: Codex Alimentarius Commission and the WTO

During the initial discussions that established the CAC, the officials and experts considered protecting the health of consumers and ensuring fair practices in food trade to be the primary purpose of CAC. They were of the opinion that if all countries harmonised the food laws and incorporated similar international food standards, the preliminary purpose of health and fair trade practices would be served.[201] During that period many countries had introduced conflicting mandatory provisions with respect to FDMB, to minimize risk to consumer health, and CAC sought to remedy this situation by providing guidelines to promote more uniform standards.

With the Uruguay Round of agreements,[202] however, a new milestone was reached in CAC history. These agreements recognized CAC as an international standard-making body. The role played by CAC has thus become more important in promoting international food trade for both the governments and industry. The increased interests in the formulation of CAC standards, guidelines, and recommendations can be attributed to the increased awareness of two important functions of CAC. First, CAC supports member countries by providing guidelines on which national policies can be built. Hence, developing countries that lack resources to develop adequate food regulatory principles to ensure public health and promote trade have become aware that CAC guidelines provide the necessary information. Second, CAC supports consumers and industry alike by

---

[201] Supra note 62 at 29

[202] World Trade Organisation, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 15 April 1994, 1867 U.N.T.S. 14

protecting consumer health and safety and at the same time promoting international trade in food. Thus, industry and non-governmental organizations have become aware that CAC guidelines form the basis of food trade and have actively participated in its deliberations. CAC standards have also been given recognition in the WTO Agreements as a standard by which disputes over food trade would be resolved.[203]

Given the economic and trade implications of the CAC guidelines or standards, labelling of FDMB was one of the most highly debated issue at CCFL and CAC. Elaborate deliberations about the scope, application, traceability, documentation, verification, and safety of foods derived from modern biotechnology engulfed the CCFL for 18 years. "The standard setting process of the Codex Alimentarius has inevitably ended up being politicized – sometimes to the point of a stalemate."[204] All countries realized the importance of this issue and wanted to adopt a guideline; however, there was no consensus on the exact nature of the guideline. The consequences that could emerge at the WTO from a CAC guideline was partly the reason for the lack of consensus in determining a standard for labelling FDMB.

Two of the WTO agreements quote CAC standards as a reference point for the settlement of international food trade disputes. First, the Agreement on Application of Sanitary and

---

[203] Mark Mansour & Jennifer B. Bennet, "Codex Alimentarius, Biotechnoloogy and technical barriers to trade", online: (2000) 3:4 Agbioforum at 213 <http://www.agbioforum.org/v3n4/v3n4a06-mansour.htm>
[204] Peter H. Sand, "Labelling Genetically Modified Food: The Right to Know" online: (2006) 15:2 Review of European Community and International Environmental Law at 189 <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-9388.2006.00520.x/pdf>

Phytosanitary Measures[205] (SPS agreement) and second, the Agreement on Technical Barriers to Trade[206] (TBT agreement). The overall objective of these agreements is to prevent national standards and legislation from becoming barriers to trade and to promote free and fair access to international markets. Article 12 (3) of the SPS agreement specifically recognizes CAC standards, guidelines, or recommendation as a source of scientific advice and Article 12(4) states that international guidelines form the basis for setting import standards for sanitary and phytosaniatry measures. Similarly Article 2.4 of the TBT agreement recognizes all international standards work including the CAC as authoritative in determining trade barrier issues.[207] This recognition in both the Agreements above designates the CAC "as a benchmark authority for global standard setting in the WTO context."[208]

Should any dispute arise between member countries regarding the application of the agreements of the WTO, governments have recourse to the procedures established under the Dispute Settlement Understanding (DSU).[209] Article 3 of the DSU states that the function of the system is to preserve the rights and obligations of its members under the covered agreements. The system attempts to clarify the existing provisions of the covered agreements on the basis of the text of the agreements and any explicit reference included

---

[205] Marrakesh Agreement Establishing the World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures,15 April 1994, 1867 U.N.T.S. 493 <http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm>

[206] Marrakesh Agreement Establishing the World Trade Organization, Agreement on Technical Barriers to Trade, 15 April 1994, 1867 U.N.T.S. 493 <http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm>

[207] John R. Lupien, "The Codex Alimentarius Commission: International science based standards guidelines and recommendations", online: (2000) 3:4 Agbioforum at 192 <http://www.agbioforum.org/v3n4/v3n4a02-lupien.htm>

[208] Supra note 204 at 189

[209] General Agreement on Tariffs and Trade 1994, Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 187

in them.[210] All requests for conciliation are heard by the Dispute Settlement Board (DSB).

Even though the WTO is not responsible for developing food safety standards it does have the authority to identify standards that restrict international food trade.[211] So, national standards that are unjustified and act as barriers to the access of international markets can be referred to the WTO for its review. Some of the issues that will be important in understanding the role of WTO in labelling of food derived from modern biotechnology are:

- Which WTO agreements apply when labelling requirements and product- tracing requirements pursue multiple policy objectives.
- Whether GM foods are like other products to non GM foods for the purpose of Article 2 (1) of the TBT agreement and Article III(4) of GATT 1994.
- What the likely impact of labelling and product- tracing requirements are for the competitive opportunities for GM food with respect to Article 2 (1) of the TBT agreement and Article III(4) of GATT 1994.[212]

It is first necessary to determine which agreement could apply in the event a dispute were to arise with respect to labelling of FDMB. Second, it is necessary to understand the possible grounds on which conciliation could be requested by member countries. Third, it is imperative to determine the WTO's understanding of the likely impact of labelling of FDMB on their marketability.

---

[210] Supra note 203 at 216
[211] Supra note 203 at 217
[212] David Morgan and Gavin Goh, "Genetically modified food labelling and the WTO agreement", online: (2004) 13: 3 RECIEL at 309 < http://onlinelibrary.wiley.com>

4.1 Applicable Agreements:

Some of the agreements that could apply to a dispute on labelling of FDMB are contained in the General Agreement on Tariffs and Trade and two of its supplementary agreements, the SPS Agreement and the TBT Agreement. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity[213] is also applicable, although to limited extent, as it has an indirect impact on labelling at the consumer level. It establishes an advance informed agreement (AIA) procedure to enable countries to make informed decisions before agreeing to the import of living modified organisms into their territory through labelling.[214]

4.1 (a) General Agreement on Tariffs and Trade (GATT)

GATT contains the general obligations of member countries with respect to international trade, and Article XX of GATT provides limited exceptions to the application of the general obligations. Article III of GATT[215] requires that member countries give importers the same treatment as those accorded to products of national origin. The WTO holds that the intent of Article III is to "provide equality of competitive conditions for imported products in relation to domestic products."[216] Applying this principle, it would not be GATT compliant to promote FDMB from national producers yet ban imports. However,

---

[213] The Convention on Biological Diversity, " Cartagena Protocol on Biosafety", (adopted on 29 January 2000) < https://bch.cbd.int/protocol/text/>

[214] These identification requirements vary depending on the intended use of the Living Modified Organisms. Accordingly, there are different requirements for Living Modified Organisms intended for direct use as food or feed, or for processing,destined for contained use and for intentional introduction into the environment. As these rules are relevant to import and export Living Modified Organisms and has no direct consequent on domestic labelling requirement it has not been elaborated herein - Ibid at Article 18.

[215] Supra note 209 at Article III

[216] Japan Taxes on Alcoholic beverages, (1996), WT/DS8/AB/R at para16 (Appellate Body Report) online: WTO <<http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds8_e.htm>

how the WTO would consider a dispute on banning FDMB while allowing imports of its conventional counterparts would be based on how similar the WTO considered the categories of goods .

In the Japan – Taxes on Alcoholic Beverages dispute, the European Communities, Canada, and United States claimed that spirits exported to Japan were discriminated against under the Japanese liquor tax system. The DSB clarified how "like products" as contained in Article III.2 would be determined:

> "likeness" of products must be examined taking into account not only objective criteria (such as composition and manufacturing processes of products) but also the more subjective consumers' viewpoint (such as consumption and use by consumers) …. Since consumer habits are variable in time and space and the aim of Article III:2 of ensuring neutrality of internal taxation as regards competition between imported and domestic like products could not be achieved if differential taxes could be used to crystallize consumer preferences for traditional domestic products…. Even if imported alcoholic beverages (e.g. vodka) were not considered to be "like" to Japanese alcoholic beverages (e.g. shochu Group A), the flexibility in the use of alcoholic drinks and their common characteristics often offered an alternative choice for consumers leading to a competitive relationship. In the view of the Panel there existed – even if not necessarily in respect of all the economic uses to which the product may be put – direct competition or substitutability among the various distilled liquors, among various liqueurs, among unsweetened and sweetened wines, and among sparkling wines. The increasing imports of "Western-style" alcoholic beverages into Japan bore witness to this lasting competitive relationship and to the potential products substitution through trade among various alcoholic beverages. Since consumer habits vis-à-vis these products varied in response to their respective prices, their availability through trade and their other competitive inter-relationships, the Panel concluded that the following alcoholic beverages could be considered to be "directly competitive or substitutable products" in terms of Article III:2.[217]

[217]Japan-Taxes on Alcoholic beverages, 1996, WT/DS11/R, at 5.7, (Panel Report), online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds8_e.htm>

Thus a "like product" is determined based on characteristics, manufacturing process, consumer perceptions and preferences, end use, competitive inter-relationship, and substitutability between the products. The DSB Panel considered the operation of all the above factors as a whole in determining whether two products could be considered as "like products." In "European Communities – Measures Affecting Asbestos and Asbestos-Containing Products"[218] the Appellate Body (AB) of the WTO held that "health risks" should also be considered in determining "likeness."

Applying the above test in a comparison of FDMB to their conventional counterparts, the characteristics, manufacturing process, potential health risks, end use, competitive relationship with conventional counterparts, consumer perceptions, and preferences could very well be the determining factors in the event of a WTO challenge.

Further, Article XX(b) GATT[219] states the exceptions to Article III; it recognizes the right of member countries to develop policies that "protect human, plant and animal health and safety." A request for conciliation could be made with respect to testing, inspection, certification, approval procedures, quarantine treatments, sampling procedures, and risk assessment methods in a regulation with respect to FDMB. In such a case, a country will have to justify that its regulation of a particular FDMB is required to protect human, plant and animal health and safety even though the FDMB may be considered as a "like product".

---

[218] European Communities – Measures Affecting Asbestos and Asbestos- Containing Products, (2000), WT/DS135/AB/R, (Appellate Board Report),online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds135_e.htm>

[219] Supra note 209 at Article XX(b)

This exception was discussed by the DSB in "European Communities – Measures Affecting Asbestos and Asbestos-Containing Products Case."[220] In 1998, Canada requested consultations with the EC with respect to measures imposed by France regarding the prohibition of asbestos and products containing asbestos, including a ban on imports of such goods. In 1997, France prohibited the manufacture, processing, sale, importation, exportation, domestic marketing, possession for sale, offer, and transfer of all varieties of asbestos fibres, regardless of whether these substances have been incorporated into materials, products, or devices. Canada challenged the ban on chrysotile fibre and products containing it. Canada stated that chrysotile fibre was not like amphibole fibres, the asbestos most hazardous to health, and thereby the ban was not justified.

The AB held that the products were alike because the end uses were the same and they were substitutes of each other. With reference to exception XX(b) of GATT, the AB held that.

> … there is no requirement under Article XX(b) of the GATT 1994 to quantify, as such, the risk to human life or health. A risk may be evaluated either in quantitative or qualitative terms. In this case, contrary to what is suggested by Canada, the Panel assessed the nature and the character of the risk posed by chrysotile-cement products. The Panel found, on the basis of the scientific evidence, that "no minimum threshold of level of exposure or duration of exposure has been identified with regard to the risk of pathologies associated with chrysotile, except for asbestosis." The pathologies which the Panel identified as being associated with chrysotile are of a very serious nature, namely lung cancer and mesothelioma, which is also a form of cancer…[221]

---

[220] Supra note 218
[221] Supra note 218 at para 167

The AB held that for the exception of protection of public health to be upheld it must be proven on scientific basis that there is possible harm to the public.

4.1 (b) The SPS Agreement

The SPS Agreement permits WTO members to apply measures necessary for the protection of human, animal or plant life, or health.[222] Measures that conform to the SPS Agreement are presumed to be in accordance with GATT provisions.[223] SPS measures may relate to process and production methods, testing, inspection, certification, approval procedures, quarantine treatments, sampling procedures, risk assessment methods and packaging, and labelling requirements related to food safety.[224] The measures adopted by member countries should be based on scientific principles and sufficient scientific evidence, and should not be more trade restrictive than necessary to achieve the appropriate level of sanitary and phytosanitary protection.[225] Annexure A to the SPS Agreement suggests that the purpose of the regulation also be considered.

Thus a labelling policy must be justified as a measure to protect against risks from pests or diseases or food borne risks to human, animal, and plant health and safety and will need to be decided on a case-to-case basis. Article 5.1 of the SPS Agreement[226] states that:

> Members shall ensure that their sanitary or phytosanitary measures are based

---

[222] Supra note 205 at Article 2(4)
[223] Supra note 209 Article XX(b)
[224] Supra note 205 at Annex para 1
[225] Supra note 205 at Article 2.2
[226] Supra note 205 at Article 5.1

> on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

This article is important, keeping in mind the current Compilation. The Principles for Risk Analysis of Foods derived from Modern Biotechnology, which is one of the texts in the Compilation, specifically mentions labelling as tool for post-market monitoring. Given that the SPS Agreement recognizes CAC guidelines, a mandatory labelling regulation could only be challenged on grounds of scientific evidence.

Further, the SPS Agreement recognizes the precautionary principle, and Article 5.7 dealing with the treatment of scientific evidence states that:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.[227]

Member countries may choose to adopt labelling regulations based on the precautionary principle. As stated above[228], this principle has been the subject of varied interpretation. According to Article 5.7, a labelling policy could be adopted based on the precautionary principle when there is a lack of relevant scientific evidence, based on international standards, to support the safe use.[229] Given this requirement, one can understand clearly

---

[227] Supra note 205 at art.5.7
[228] Supra note 51
[229] Ian Sheldon & Tim Josling, "Biotechnology Regulations and the WTO", working paper 02-2, online: (2002) International Agricultural trade Research Consortium at 14 <http:// www.iatrcweb.org>

why CCFL decided to proceed with the matter of labelling of FDMB, despite the lack of consensus for such a long time. Developing countries that lack resources are dependent on the scientific principles adopted by CAC, for developing their regulations on approval and commercialization and management of foods derived from modern biotechnology. Secondly, even developed countries can use the approved standards to challenge or justify their labelling regulations.

The DSB considered for the first time Article 5.7 of the SPS Agreement in the European Commission – Measures concerning meat and meat products (Hormones).[230] In this case the US claimed that the EC measures to ban import of meat and meat products containing bovine growth hormones (BGH) was inconsistent with Articles III or XI of the GATT 1994, Articles 2, 3 and 5 of the SPS Agreement. The EU invoked the precautionary principle, since there does not seem to be conclusive evidence that BGH meat is damaging for human health. The AB ruled that the EU violated article 5.1 of the SPS agreement, since the measure was not sufficiently based on a risk assessment. The EU has chosen to keep the ban, and pay trade sanctions to the US and Canada, something the EU in its turn is challenging, since it claims that it has made sufficient changes to its import restricting measures.

The AB in this case commented on the use of precautionary principle with foods derived from modern biotechnology as follows;

---

[230] European Commission – Measures concerning meat and meat products (Hormones), (2009), WT/DS48/AB/R, (Appellate Board Report), online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm>

> It appears to us important, nevertheless, to note some aspects of the relationship of the precautionary principle to the SPS Agreement. First, the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement. We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.[231]

The AB acknowledged that Article 5.7 recognized the precautionary principle without an explicit reference to it. They also recognized members' rights to use precaution where there were risks of irreversible harm. However, it stated that the use of the principle alone was not sufficient to uphold any inconsistencies with the obligations under the SPS Agreement.

The AB again considered the application of Article 5.7 in Japan – Measures Affecting Agricultural Products.[232] The US challenged Japan for its measures that restricted the

---

[231] Ibid at VI

[232] Japan – Measures Affecting Agricultural Products, (1999), WT/DS76/AB/R, (Appellate Board Report), online: WTO < http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds76_e.htm>

import of certain agricultural products to prevent the introduction of fire blight, a disease targeting apples and other fruits. The measures were challenged under the SPS agreement. The AB ruled that article 5.7 of the SPS agreement is not triggered by scientific uncertainty, but by insufficient evidence.

The condition of "reasonable period of time" in Article 5.7 indicates that such measures are temporary.[233] There is no fixed period of time mentioned and it would depend on the basis of scientific evidence present. The Principles for Risk Analysis of Foods Derived from Modern Biotechnology, adopted by Codex, also requires that risk analysis be reviewed periodically based on advances in science and technology.[234] Applying the above requirements to the labelling of foods derived from modern biotechnology could be adopted on a case-by-case basis for a reasonable period of time and it would have to be reviewed intermittently, or as and when new evidence arose.

4.1 (c) The TBT Agreement

The TBT Agreement encompasses a broader range of domestic regulation. The TBT Agreement distinguishes between standards that are mandatory and those that are non-mandatory technical regulations. A technical regulation has been defined as follows:

> Document which lays down product characteristics or their related processes and production methods including the applicable administrative provisions with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as

233 Ellie Cijvat, Genetically modified organisms and the World Trade Organization, (M Sc. Thesis, IIIEE Lund, Sweden, 2006) [unpublished]
234 Supra note 192

they apply to a product, process or production method.[235]

Thus any labelling regulation that covers characteristics of the products would be covered by the TBT Agreement. The TBT Agreement imposes substantive obligations on any regulation or legislation that meets with the definition of a technical regulation. Some of the obligations are like treatment to similar products, satisfaction of a least trade restrictive test, legitimate objective based on a relevant international standard where such standards exist, or cases where such regulations are required.[236] It is important to note that both the "SPS and TBT agreements acknowledge the importance of harmonizing standards internationally so as to minimize or eliminate the risk of sanitary, phytosanitary and other technical standards becoming barriers to trade."[237]

A review of the provisions of the WTO agreements above indicates that the objective of the labelling policy is very important as it could be the deciding factor in determining whether the national policy is WTO compliant or not. The vast differences among member countries with respect to the objective of labelling foods derived from modern biotechnology has made this issue a fertile ground for future disputes.

The EU labelling regulation, for example, describes one of its purposes as being able to "ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced there from, so as to allow them to make an informed choice of

[235] Supra note 206206 at Annex 1para1
[236] Supra note 206 at Article 2.2 and 2.3
[237] Supra note 62 at 31

product."[238] In public statements the EU has described the purpose of its overall regulation on GMOs as including the protection of human health and environment.[239] Mandatory labelling requirements with such a purpose may fall under the scope of the SPS agreement; however, a general labelling requirement with an indirect reference to food safety cannot be so clearly identified and could lead to confusion.[240]

Labelling requirements that allow consumers to make informed choices about products to prevent misleading or deceptive practices or for ethical, moral, or religious concerns would normally fall under the scope of the TBT Agreement. The issue to be considered in such disputes will be whether such labelling regulations are consistent with the non-discriminatory obligations to prevent restrictive barriers to trade and the achievement of a legitimate objective as detailed in article 2(1) and 2(2) of the TBT Agreement.[241] Article 2(2) sets out an indicative list of legitimate objectives that includes prevention of deceptive practices, protection of human health and safety, animal and plant life health and safety, and safety of the environment.[242] Mandatory labelling legislation with the purpose of informing consumers would be considered as a legitimate objective under Article 2(2). However, in the event of a dispute the criteria that the DSB will have to consider is whether or not such measures are "more trade-restrictive than necessary to fulfil the legitimate objective."[243]

---

[238] Supra note 6 at para 11
[239] EC, European commission on the regulation of GMOs in the EU /02/160 of July 2003, (2003) Annex 5 at 1
[240] Supra note 212
[241] Supra note 206 at Art 2(1) and Art 2(2)
[242] Supra note 206 at Article 2(2)
[243] Supra note 212 at 313

Given the difference between mandatory and voluntary labelling approaches, the controversy surrounding labelling of FDMB is bound to persist. By not supporting any particular model of labelling the Compilation has not addressed this confusion. The WTO dispute settlement panel will still have to face requisitions for conciliation in disputes of labelling practices as being discriminatory and restrictive and thereby hindering free and fair international food trade. The WTO approach for determination on a case-by-cases basis combined with the political understanding of withdrawal in certain cases has led to the lack of consistency on how disputes with respect to labelling will be treated.

4.2 Are Foods Derived from Modern Biotechnology Similar to Their Conventional Counterparts?

Whether FDMB are similar to their conventional counterparts will be relevant to the labelling. If foods are like the conventional counterparts then the labelling regulations will be compared to the labelling regulations of the conventional counterparts to determine if there is a discrimination as contained in Article III of GATT.[244]

The like products test developed in the Japan Alcoholic Beverages Tax law dispute[245] will be applied to determine if FDMB are similar to their conventional counterparts. Whether FDMB are like their conventional counterparts, in terms of product properties, nature, and quality has to be determined on case-by-case basis.

---

[244] Supra note 212 at 315
[245] Supra note 216.

Consumer preferences in determining whether FDMB are similar to their conventional counterparts is also another factor identified by the WTO in the European Communities – Measures Affecting Asbestos and Asbestos-Containing Products Case.[246] "Consumer preferences may be based on perceived environmental, safety, or quality or property of goods. Such preferences may be or may not be expressed in the physical characteristics of the product but may relate to its method of processing or production..."[247] These preferences vary over time and also with the amount of information that is available to the consumer.

The Compilation is based on the consideration that FDMB are not necessarily different from their conventional counterparts, based solely on the method of production. This understanding might provide some direction in future disputes at the WTO. The health risks associated with the product will be a relevant issue to determine likeness based on physical properties. Hence, scientific justification of a labelling requirement may well become the primary ground on which labelling of FDMB can be justified.

4.3 Competitive Opportunities:

Competitive Opportunities refers to market conditions. The WTO in "Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef",[248] has dealt with this issue. Article III(4) of GATT dealing with the "Nation Treatment and International Taxation and

---

[246] Supra note 218
[247] Supra note 212 at 316
[248] Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef, (2001), WT/DS161/AB/R and WT/DS169/AB/R (AB-2000-8), at paras 135–137 (Report of the Appellant Body), online: W.T.O. <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds161_e.htm>

Regulation ” states

> The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.

In this dispute, Australia and US challenged the Korean measures that affected the importation of certain beef products. The Korean government had adopted measures that supported their domestic beef industry and Korean agriculture. It also promoted separate retail distribution channels for imported beef products along with other retail measures that affected the market of imported beef. The WTO held that, the separate channel was more trade-restrictive than necessary. “Conditions of competition” includes any condition that could affect imported goods and favour domestic products.[249] The AB at the DSB found the Korean measures to be inconsistent with the requirements of the Article III(4) of GATT and hence asked Korea to amend its laws.

Thus member countries have to provide equal market access to both domestic and imported goods, and thereby any conditions that affect the marketability of imported goods could be considered a violation of this article. If FDMB are considered similar to their conventional counterparts, then the requirement of labelling could be challenged as affecting marketability due to (a) consumer perceptions and (b) increase in costs.

[249] Supra note 212 at 318

4.3 (a) Consumer perceptions

Consumer perceptions about the product directly affect the demand for the product. Consumers do not readily accept FDMB and some of the concerns raised are as follows:

> GM food is viewed by many consumers as an undesirable attribute. This view has been criticized by some scientists and industry members. Nonetheless, numbers of consumers express wariness of GM food: the introduction of GM food is not seen to have arisen from the requests of consumers and does not provide conclusive consumer benefits of improved quality and safety; GM food is viewed by some to be new, different and without demonstrated long-term evidence of safe use; its introduction and use appear to benefit mainly large corporations and farmers and reflect their interests, rather than the public interest; and its production may introduce unintended and irreversible genetic changes in the surrounding environment.[250]

The requirement for labelling amid this widespread negative perception of FDMB would directly affect marketability. The crucial factor to be determined is whether, labelling is a tool to address negative perceptions of consumer or whether labelling creates negative perceptions about safety of food.[251] The AB in the Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef,[252] found that labelling indicating that the products were imported created negative perceptions among consumers and hence affected the marketability of such products. This was considered to be a violation of Article III(4) of GATT.[253] With labelling of FDMB it is difficult to determine whether labelling creates negative consumer perceptions or it addresses consumers concerns.

The ability of labelling to impact consumer preferences was recognized by the AB in

---

[250] Michele Veeman, "Labelling Policy for GM Foods: Pragmatism in Action or Policy Failure?", online: (2003) 4 Current Agriculture, Food & Resource Issues at 109 <http://ageconsearch.umn.edu/bitstream/45733/2/veeman4-1%5b1%5d.pdf>
[251] Supra note 212 at 318
[252] Supra note 248
[253] Supra note 248 at para 198 and 640

European Commission – Trade Description of Sardines.[254] Peru challenged the European regulation that prevented Peruvian exporters from using the trade description of "sardines." According to Peru their export of "sardinops sagax sagax" are listed among those species that can be traded as "sardines" in the CAC Standard dealing with labelling and packaging of foods. The European Communities stated that its consumers associated the term "sardines" exclusively with "Sardina pilchardus" and hence its regulation restricting the use of the term sardines to "Sardina pilchardus" was justified. The Panel Report rejected the European Communities claim and the same was upheld by the Appellant body. The Panel Report stated:

> If we were to accept that a WTO Member can "create" consumer expectations and thereafter find justification for the trade-restrictive measure which created those consumer expectations, we would be endorsing the permissibility of "self-justifying" regulatory trade barriers. Indeed, the danger is that Members, by shaping consumer expectations through regulatory intervention in the market, would be able to justify thereafter the legitimacy of that very same regulatory intervention on the basis of the governmentally created consumer expectations. Mindful of this concern, we will proceed to examine whether the evidence and legal arguments before us demonstrate that consumers in most member States of the European Communities have always associated the common name "sardines" exclusively with Sardina pilchardus and that the use of "sardines" in conjunction with "Pacific," "Peruvian" or "Sardinops sagax" would therefore not enable European consumers to distinguish between products made from Sardinops sagax and Sardina pilchardus.[255]

Accordingly, it is necessary to establish consumer expectations or perceptions objectively. Given the variable nature of this criteria, this would be difficult to achieve. Thus labelling regulations have to be justified on scientific evidence in order to withstand any challenge, as they have the potential to encourage adverse consumer perceptions.

---

[254]European Commission- Trade Description of Sardines, (2002), WT/DS231/R, (Panel Report), online: WTO < http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds231_e.htm>
[255] Ibid at para 7.127

4.3 (b) Compliance Costs

The other important factor that could affect competitive opportunities of FDMB is the cost of complying with the labelling requirements. Increased cost due to mandatory labelling has been cited as one of the factors for adopting a voluntary model of labelling. The major cost of labelling arises from identity preservation and associated segregation systems.[256] Identity preservation refers to documentation about the source of the food and segregation systems refers to infrastructure to keep GM food separate from conventional food. Whether a labelling requirement would increase cost or not remains debatable. Several studies have indicated different numbers. The EC, however, considers that the "transmission and retention of information can be largely incorporated into existing documentary systems for transactions and as such should not imply significant extra costs for operators and consumers."[257]

A number of studies have indicated that the cost of segregation and identity preservation. Cost of labelling depends on several critical characteristics such as "the threshold level, the capacity of the industry to comply with requirements, and the public authority's capacity to enforce the labeling rules."[258] The cost of labelling ranges from USD48/person/year to as low as USD3.50/person/year.[259] In 2000, the EC commissioned a study that estimated that the price increase for identity preservation alone ranged from

---

[256] Sangeetha Bansal, Bharat Ramaswamy, "Labels for GM foods; what can they do?", online: (2010) Economic and Political Weekly < http://cera-gmc.org/docs/sabp_reports/bansal_ramaswami_2010.pdf>
[257] Supra note 212 at 319
[258] Guillaume P. Gruere and S.R. Rao, "Review of International Labelling policies of genetically modified food to evaluate India's proposed rule", online: (2007) 10;1 Agbioforum at 56 <http://www.agbioforum.org/v10n1/v10n1a06-gruere.pdf>
[259] Ibid

6% to 17% in farm-gate prices.[260] The studies have been conducted from 2000 to 2006 to review the feasibility of mandatory labelling model. The criteria for assessments have varied and so have the location. National studies have been published for Canada, Australia, New Zealand, United Kingdom, and the Philippines.[261] In the United States it has been argued that segregation system for soybeans and maize could increase the price of the conventional counterparts by as much as 100%.[262] Moreover, identity preservation and testing would be required to ensure that the foods had been effectively separated, and such testing could add as much as 30% to the final food product.[263]

The cost of labelling could affect the competitive opportunities of foods derived from modern biotechnology in comparison to their conventional counterparts. The above challenges highlight the various situations for future disputes before the WTO. The Compilation has not been able to address these concerns, and the complexity of the matter makes it almost inevitable that they are decided on a case-by-case basis.

4.4 WTO and the "European Communities – Measures Affecting the Approval and Marketing of Biotech Products"

One of the disputes that considered several concerns raised with respect to the approval and adoption of foods derived from modern biotechnology is the "European Communities

---

[260] Commission of European Committees, Economic Impacts of Genetically Modified Crops on the Agri Food Sector, A first Review (2000)
[261] Supra note 258 at 56
[262] "Public hostility to the genetic modification of crops risks slowing down the development of a potentially important technology—which is why more must be done to reassure consumers", The Economist, (17 June 1999), online: The Economist, http://www.economist.com/node/213511
263"Sticky labels", The Economist, (29 April 1999), online: The Economist, < http://www.economist.com/node/321496>

– Measures Affecting the Approval and Marketing of Biotech Products."[264] Although this cases did not consider labelling, it has dealt with several provisions in the applicable agreements and is relevant to any future disputes on FDMB.

In this case Argentina complained that the European Union laws regarding the approval and marketing of foods containing GMOs had violated The SPS Agreement, the TBT Agreement, and provisions of GATT. In its request Argentina asserted:

> 1. The existence of the alleged moratorium is a violation of the SPS rules against "undue delay" in SPS agreement approval procedures;
> 2. Failure to notify the moratorium as an SPS measure is a violation of SPS agreement rules on transparency of rule making and notification of domestic SPS measures to the WTO SPS committee;
> 3. The EC [European Commission] and EC [EU] member states failed to publish risk assessments on the likelihood of harm resulting from biotech products as required by article 5.1;
> 4. The alleged moratoria are maintained without "sufficient scientific evidence" in violation of article 2.2;
> 5. By regulating biotech products, such as genetically engineered seeds, more strictly than biotech processing agents, such as enzymes used in food manufacturing, the EC violates article 5.5, which seeks to ensure that WTO agreements apply SPS measures indiscriminately to domestic and imported products "in comparable situations.[265]

Australia, Brazil, Canada, India, Mexico, New Zealand, and US requested to join the consultations. A panel was set up, and the EC responded by denying the existence of a moratorium. With respect to the actions of some member countries it stated that such measures were provisional and permitted under Article 5.7 of SPS Agreement.[266] The Panel rejected this claim and stated that a de facto moratorium had in fact existed and this

---

264 European Communities — Measures Affecting the Approval and Marketing of Biotech Products,(2006), WT/DS291/R,WT/DS292/R,WT/DS293/R, (Panel Report), online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm>
265 Supra note 233 at 4.3.1
266 Supra note 264 at para. 4.373-4.378

had unduly delayed the approval of several products derived from modern biotechnology. Further, the provisional measures as detailed in 5.7 required that risks be based on the assertion that there is insufficient scientific evidence to support acceptance. It stated:

> The language in Article 5.7 does not exclude the applicability of all other SPS provisions simply on the basis that the measures in question are provisional. The starting point for an analysis of an SPS measure is Article 2. It establishes basic rights and obligations of the Members with respect to their SPS measures. Such measures must be based on scientific principles and must not be maintained without sufficient scientific evidence. Whether the measures are provisional or not is beside the point.[267]

The Panel held that there should be scientific evidence in risk assessment that warrant safety measures whether such measures are provisional or not. The Panel went on further to review the adoption of Article 5.5 of the SPS Agreement in the EU members. It reiterated the need for scientific evidence to justify the regulation of biotech products, such as regulating genetically engineered seeds, more strictly than biotech processing agents, such as enzymes used in further food manufacturing processes. The Report stated:

> When the European Communities' own experts unambiguously find that there is no evidence to show that these products are unsafe, and the member States nevertheless ban the products and maintain those bans in the face of further scientific advice that such bans are groundless, this cannot be characterized as anything other than a complete disregard or determination to ignore such opinions and advice. When this is done on a selective basis that bears no relationship to the actual risks involved, the conclusion is inescapable that the resulting measures give rise to a violation of Article 5.5.

In brief, the Panel concluded that the de facto moratorium and 24 product-specific measures had caused undue delay. With respect to the safeguard measures adopted by member countries, the Panel ruled it to be incompatible with Articles 5.1 and 2.2 of the

[267] Supra note 264 at para 4.438

SPS Agreement because the measures were not based on risk assessments satisfying the definition of the SPS Agreement and hence could be presumed to be maintained without sufficient scientific evidence. The European Communities accepted the Panel Report and requested for time to implement findings. On 19 March 2010, Argentina and the European Union notified the DSB of a mutually agreed solution. The parties agreed to establish a bilateral dialogue on issues related to the application of biotechnology to agriculture.[268]

There were several important issues that were not referred to in this dispute, such as whether FDMB are safe, whether they are to be considered "like products," or whether member countries can design their own risk assessments. The labelling of FDMB was also not considered, as it was not the subject of this dispute.[269] Even though these are very important concerns it is difficult to make a generalization and would have to be determined on a case-by-case basis (Compilation, however, has addressed the issue of standardization of risk assessment procedures). The above case highlighted the role played by scientific evidence and applying the same to labelling will ensure that scientific evidence is a crucial factor in determining the validity of a labelling approach.

The Compilation has reiterated the significance of science and has incorporated into a single text all the texts that member countries would need to consider to develop a labelling policy. Even though the Compilation recognizes labelling as a tool of post-market monitoring, it is necessary to be able to justify the perceived risk on scientific grounds. It is interesting to note that there have been no discussions about the threshold

---

[268] "Dispute Settlement of European Communities – Measures Affecting the Approval and Marketing of Biotech Products" WTO, (19 March 2010), online: <The WTO http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm>

[269] Supra note 233 at 54

limit or about verification at the WTO – some of the concerns that remained unaddressed even in the Compilation. The nature of the problem along with opposite political perceptions has left the issue of labelling of FDMB as a minefield to be defused on a case-by-case basis.

Chapter 5: Models of Labelling

5.1 Background

The complex discussions at CCFL and CAC revealed the vast differences in the perception and regulation of genetically modified food between countries. Below is a summary of some of the policy considerations and the options that have been adopted by countries around the world. The complexity of the problem is compounded by the fact that there are variations within the options that have been summarized below.[270]

Policy Questions	Some Policy Options
How are genetic engineering, genetic modification, or biotechnology defined?	(a) Broadly (b) By specific techniques used
Is program voluntary or mandatory?	(a) Voluntary for non-GMO and/or GMO (b) Mandatory for GMO (c) Mandatory for GMO and non-GMO
Which products are covered by the policy?	(a) All food products (b) Only key food products (c) Only certain food categories
Which ingredients are covered?	(a) All ingredients (b) Only most important ingredients (c)All ingredients except preservatives, additives, etc.
When are labelling requirements triggered?	(a) X% of product is GM (b) Most important ingredients are GM (c) Important characteristics are altered
How are products made from animals fed with GM inputs handled?	(a) Labelling required if feed is GM (b) Labelling not required if feed is GM

[270] J.A.Caswell, "Labelling Policy for GMOs:To each his own", online: (2000) 3:1 Agbioforum at 55 < http://agbioforum.org/v3n1/v3n1a08-caswell.htm>

How are restaurant, take-out, bulk, and institutional foods handled?	(a) Included in labelling requirements (b) Excluded from labelling requirements
What label statements must/can be made?	(a) Does contain GMOs (genetically modified) (b) May contain GMOs (may be genetically modified) (c) Non-GMO (d) Does not contain GMOs
How are companies required to verify GM status?	(a) Self-certification by seller is acceptable (b) Testing (c) Third-party certification
Can non-GMO labelling be used on products where there are no GM alternatives?	(a) Yes (b) No

Several food crises in Europe in the 1990s in Europe created a general mistrust among consumers about the regulatory framework and safety of genetically modified food.[271] This channelled the development of legislation to regulate genetically modified food in Europe. The lack of a similar food crisis in North America contributes to the approach of regulations for the approval and sale of FDMB in this continent. The EU has adopted a mandatory model of labelling, whereas the US and Canada have adopted a voluntary model of labelling of foods derived from modern biotechnology. The mandatory model adopted in the EU requires tracing and labelling from 'farm to fork'. The voluntary labelling model is based on the principle that FDMB are generally regarded as safe due to the fact that they undergo extensive tests during its development and approval.

As discussed above, labelling proposes to inform the consumer about the product's

[271] Supra note 1 at 541

unobservable nature and characteristics. It is an important tool that has a decisive impact on consumers and hence is sought to be thoroughly regulated. Whether a product contains genetically modified ingredients is impossible to determine without conducting verifications tests. Labelling has been considered a technique to deliver such information to the consumers. The impact of labelling has been summarised as below:

> Labeling affects the entire supply chain for food products. It requires definition of the attribute to be labeled (i.e., what is a "GMO"?) and segregation of products with and without the characteristics throughout the supply chain from seed inputs to the supermarket shelf. Because of this effect, labelling policy can be, and is even more frequently perceived to be, a Trojan horse bearing a broader policy and attitude toward the acceptance of GMOs in food products.[272]

The different opinions on whether this information should be made available to consumers have provided us with two alternative methods of labelling, mandatory and voluntary. This chapter analyzes and compares the mandatory labelling model, with specific reference to the United Kingdom, with the voluntary labelling model, with specific reference to Canada.

5.2 Mandatory Model and Its Adoption in the European Union.

In the European Union, mandatory labelling is based on the belief that consumers have a "Right to Know." Article 27 of The Treaty of Amsterdam[273] sought to amend Article 129(a) of The Treaty Establishing European Union,[274] in 1997 to give consumer

---

[272] Supra note 270 at 54

[273] Treaty of Amsterdam amending The Treaty of European Union, EU, 10 November 1997 <http://eur-lex.europa.eu/en/treaties/dat/11997D/htm/11997D.html>

[274] Consolidated version of The Treaty Establishing the European Community, EU, 24 December 2002, OJ C325/35, < http://www.frontex.europa.eu/assets/Legal_basis/12002E_EN.pdf>

protection a legal status. The Amended Treaty Establishing the European Union in Article 153 provides the basis for the "Consumer's Right to Know" in the EU. The Article states:

> In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.[275]

The above Article directly addresses the consumer's right to information and education and forms the basis of the "Consumers Right to Know" in the EU. This right to information has been the foundation for the tracing and labelling legislation in the EU. The Europa, in its summaries of legislation writes, "Information is the deciding factor for consumers when making their choices and affects both consumer interests and their confidence in the products and services within the internal market."[276] This understanding indicates the belief that providing the necessary information to consumers could enhance the confidence of consumers about the market. A survey called "The Europeans and Biotechnology 2010"[277] commissioned by the EC, monitors the acceptance level of genetically modified food and reasons for the lack of acceptance among consumers.

The 2010 survey indicates a marginal decline in the support of GM food, barring fluctuations between 1996 and 2010.[278] One has to also consider that the composition of the EU has changed over the years and that this has had an impact on the results.

---

[275] Ibid
[276] Summaries of EU legislation Consumer Information, online: Europa, , http://www.frontex.europa.eu/assets/Legal_basis/12002E_EN.pdf
[277] European Commission Directorate General for Research, "The Europeans and Biotechnology 2010", (2010) < http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf>
[278] Ibid at 36

According to the survey the primary factor deciding the support or opposition of genetically modified food is the "issue of safety." The report states [279]

> The perceived safety deficit suggests that the risk assessment for GMOs in place according to EU rules is not considered valid. It could also be interpreted as an entrenched attitudinal association between GM food and a lack of safety, notwithstanding institutional efforts to demonstrate the opposite.

The failure in communication, as indicated above, is very interesting and relevant to the debate about whether mandatory labelling is sufficient to provide the necessary information to consumers. Those who oppose the mandatory labelling model believe that labels do not provide sufficient information for consumers to make an informed choice. Genetic modification involves complex technology that is difficult to be reduced to a label.

The issue of safety of some GMOs has caused six countries in the EU to ban the use and sale of genetically modified products. This ban has been evoked under the "safeguard clause" in Article 23 of Directive 2001/18/EC.[280] The six countries are Austria, France, Germany, Greece, Hungary, and Luxembourg. Italy is contemplating a ban on GM crops but has not done so formally.[281] Directive 2001/18/EC refers to the Directive of the European Parliament and of The Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.[282] Article 23, referred to as the "safeguard clause," permits member countries to provisionally restrict or prohibit the use

---

[279] Ibid at 38
[280] Directive of the European Parliament and of The Council of 12 March 2001 on the Deliberate release into the environment of genetically modified organisms, OJC L 106/1
[281] Supra note 277 at 36.
[282] Supra note 280

and sale of genetically modified organisms if there is a sufficient scientific evidence of risk to human or environmental health.[283] An analysis of the provisional ban of GMOs in the above six countries is beyond the scope of this thesis.

The primary Regulation of the EU that forms the basis of the tracing and labelling legislation in England is the EU Traceability and Labelling regulation 1830/2003[284] and its subsequent amendment through Directive 2001/18/EC.[285] This Regulation sets out the requirements for a document audit trail to account for and identify approved GM products throughout the marketing chain. This Regulation came into force in April 2004 and was adopted after nearly two years of intense deliberations.

This Regulation along with the EU Food and Feed Regulation 1829/2003,[286] which creates a specific harmonized procedure for the scientific assessment and authorization of GM food and feed products, promotes centralized regulation for the approval and labelling of GMOs in food and animal feed. As the above two rules were adopted by regulation it does not require national implementation.[287]

The definition of GMO is contained in Directive 2001/18/EC[288] in Article 2(2) as follows:

> Genetically modified organism (GMO) means an organism, with the

[283] Ibid at Art. 23
[284] Supra note 6
[285] Supra note 280
[286] Supra note 5
[287] Andersen Lars Bracht, "The EU Rules on Labelling of Genetically Modified Foods: Mission accomplished?", online: (2010) 3 European Food and Feed Law Review at 139 < http://www.citeulike.org/user/kwongchunlong/article/8061447>
[288] Supra note 280

> exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.[289]

Thus any organism in which the heritable characteristics are altered by the use of techniques such as recombinant nucleic acid techniques (inserting nucleic acid molecules produced outside an organism into any virus, bacterial plasmid, or other vector system) and their incorporation into a host organism in which they do not occur naturally, by methods such as micro-injection, macro-injection, and micro-encapsulation, or cell fusion that do not occur naturally[290] is defined as a genetically modified organism.

This definition forms the basis of all regulation of food containing GMO and FDMB. It is is similar to the Compilation. In the Compilation, "modern biotechnology" is defined as:

> "Modern Biotechnology" means the application of: i) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or ii) Fusion of cells beyond the taxonomic family.[291]

The definition adopted by the EU is more elaborate on the techniques; however, the underlying idea is of fusion of nucleic acid molecules that does not occur naturally. The European Food Safety Authority (EFSA) is the centralized body responsible for the implementation of Directive 2001/18/EC.

Regulation (EC) No 178/2002[292] lays down the general principles for the establishment of

---

[289] Supra note 280 at Art 2(2)
[290] Supra note 280
[291] Supra note 192
[292] Regulation (EC), Commission Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down

the EFSA. The EFSA adopts harmonized procedures for the scientific assessment and authorization of genetically modified food and feed products. It is this centralized body that is in charge of conducting the risk assessment and developing the risk management policy. The Regulation requires that "risk assessment" be based on "available scientific evidence and undertaken in an independent, objective, and transparent manner."[293] This article incorporates the requirements of the Compilation with respect to risk assessment.

The "Precautionary Principle" has been recognized in this regulation. Article 7,[294] it states that precautionary measures based on identifiable possible harm with scientific certainty may be adopted on a provisional basis. This Article recognizes the commitment of member countries to the SPS Agreement. It requires that such provisional measures should not restrict trade, and that economic and trade consequences should be considered prior to implementing such precautionary measures. This incorporation of the requirements of the SPS Agreement into this regulation could help justify any labelling requirement in the event of a WTO challenge.

Further, Article 13(e)[295] states to "promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the community is not reduced." This Article specifically recognizes international standards and recommends their incorporation into existing standards. With the Compilation stating that member countries could choose a model of labelling so long as its criteria for risk

---

procedures in matters of food safety,[2002] O.J.L.31/1at Art. 1(2) < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>
[293] Ibid at Art.6(2)
[294] Ibid at Art.7
[295] Ibid at Art.13(e)

assessment and risk management are based on scientific principle (this is also specifically stated in the European Union Regulation (EC) No 178/2002), there seems to a be a consistency between the Compilation and the EU Regulations on risk assessment and risk management, at least at the theoretical level. There could, however be challenges based on the interpretation of scientific evidence used to justify precautionary measures such as labelling.

EU Traceability and Labelling regulation 1830/2003[296] sought to address the concerns about the lack of information to enable labelling of genetically modified food. The fundamental belief underlying the labelling requirements is the belief in scientific uncertainties or the possibility of unintended effects after approval.[297] The preliminary sections of the Regulation 1830/2003 summarizes the purpose:

> Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products… so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.[298]

This Regulation applies to both food and animal feed, with the purpose of providing consumers with adequate information to make an informed choice. Its objective is to provide a framework for traceability and labelling of food and feed containing genetically modified ingredients, to enable post-market monitoring on health and environment.

---

[296] Supra note 6
[297] Supra note 287 at 139
[298] Supra note 6

In order to enable tracing, all approved genetically modified organisms will be provided with unique identifies (Article 8), and all producers, processors, and suppliers shall ensure that documentation of such unique identifies are properly maintained and transferred. The labelling provision specifies the language to be used on labels and states that any product with more than 0.9% GM ingredients should be labelled. The 0.9% margin is for adventitious or technically unavoidable traces of GM ingredients. The regulation also empowers member countries to decide on procedures for inspection and control measures. The member countries can also lay down penalties for infringement of the regulations.[299]

Further, with respect to the products covered under the GMO regulations in the EU, Article 12 of Regulation EU Food and Feed Regulation 1829/2003[300] states that the labelling requirement applies to "products which are to be delivered as such to the final consumer or mass caterers ….which (a) contain or consist of GMOs; or (b) are produced from or contain ingredients produced from GMOs,"[301] that are above the threshold limit. Article 13.2(d) provides for labelling if the GM food "gives rise to ethical or religious concerns."[302] This provision indicates that labelling is decided not only on scientific basis, but it keeps in mind consumer perceptions. As discussed, consumer perceptions are also considered by the WTO in determining whether a labelling standard amounts to restrictive trade practice.

Thus, any product that is sold in the EU that has GM ingredients of more than 0.9% will

[299] Supra note 280
[300] Supra note 5 Art 12
[301] Supra note 5 at Art 12
[302] Supra note 5 at Art 13.2(d)

have to be labelled as such in the ingredients list. If foods are derived from GM plants, the regulations require labelling even though there are no traceable GM contents, for example, GM vegetables. However, there are some exceptions to this general requirement of labelling and they include refined sugar, vegetable oil, or such products where there is no DNA or protein resulting from the genetic modification present in the product. These labelling requirements also associate tracing and documentation to enable labelling.[303] It has been said that "although other countries have adopted mandatory labelling for GM food, no regulations have been as sweeping as those of the EU."[304] Even though the Regulations above seek to centralize the approval and labelling requirement to enable harmonization, the implementation is at the national level.

The Regulations and Directives detailed above deal with positive labels or labels indicating the presence of GMO. In practice however, due to the negative considerations that consumers have about GM ingredients in food, some producers wish to label their products as "GMO Free". This is referred to as negative labelling. Negative labels have a significant impact on the market "the adoption of negative labels can create significant niche markets,…..a no-GMO label might be interpreted as implying that non-labeled foods are harmful."[305] Thus the use of Negative Labels has also received significant attention.

---

[303] Steve Keane, "Can a Consumer's Right to Know Survive the WTO?: The Case of Food Labeling", online: (2006-2007) 16,Transnat'l L. & Contemp. Probs. < http://heinonline.org>
[304] Supra note 270 at 300
[305] C. F. Runge & L. A. Jackson, "Negative labeling of genetically modified organisms (GMOs): The Experience of rBST", online: (2000) 3:1 AgBioForum at 62 < http://agbioforum.org/v3n1/v3n1a09-runge.htm>

The EU Regulations do not specify any requirements for negative labelling and it is up to the national legislatures to develop policies on negative labelling.[306] All that is required according to the EU Regulations is that labels should not be misleading. Some member states such as Germany and Austria have gone beyond the EU Regulations and provided national laws or provisions to allow for the use of "GM-free" labelling. In June 2012, a decree on voluntary labelling came into effect in France on "GM Free" labelling. According to the decree to be able to use the "GM Free" label, there must be less that 0.1% of GM content in the food.[307] Hence there are three kinds of labelling in France less that 0.1% which could be labelled GM Free, 0.1% to 0.9% which does not require any labelling and above 0.9% which requires labelling as containing genetically modified ingredients.[308] However, this decree is applicable to GM food produced within France and not for imports.[309] This limitation further complicates the labelling requirements as there will be products imported into France on which there are no requirements to be labelled "GM Free" except that the GM ingredients can not be more than 0.9%. Germany and Austria are said to have similar provisions, while Netherlands has banned "GM Free" labelling.[310]

---

[306] Food Chain Evaluation Consortium Evaluation of the EU legislative framework in the field of GM food and feed, Framework contract for evaluation, impact assessment and related services, 12 July 2010, European Commission, DG SANCO at 129 <http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf>

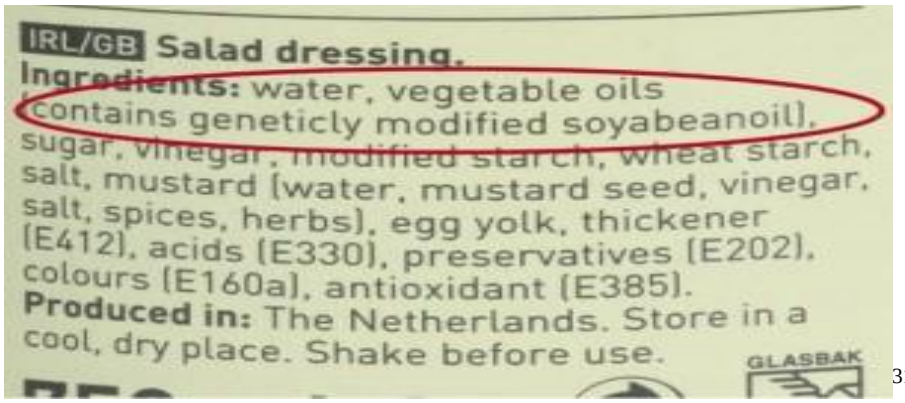
[307] "Gain Report- Non-Biotech Labeling Rules in Place and Proposed Rules on Coexistence", FR909, online: (2012) USDA Foreign Agricultural Service at 2 http://gain.fas.usda.gov

[308] John Davison, "GM plants: Science, politics and EC regulations", online:(2010), 178:2 Elsevier Plant Science < www.elsevier.com/locate/plantsci,>

[309] Supra note 307 at 2

[310] Food Chain Evaluation Consortium, "Evaluation of the EU legislative framework in the field of GM food and feed", online: (2010), European Commission, < http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf> at 133

The variations to labelling of genetically modified food even with in a centralised authorisation regime such as of the European Union, is a good indication of the complexity and near impossibility of developing a harmonised policy for labelling genetically modified food. An example of a labelling in EU is seen below:



[311]

5.2 (a) Labelling of Genetically Modified Food in England

Labelling legislation in the United Kingdom is based on Genetically Modified Organisms (Traceability and Labelling) (England) Regulation 2004.[312] This Regulation in turn is based on Regulation (EC) number 1830/2003[313] and Directive 2001/18/EC[314] discussed above. It has adopted most of the provisions of Regulation 1830/2003 and details specifically the procedures for inspection and control measures. It also enumerates the penalties for infringement of regulation 1830/2003 and Directive 2001/18/EC.

---

[311] Anthony Gucciardi**,** "Genetically Modified Food Labeling Initiative Gains Momentum in the USA" Wake Up World (7 March 2012), online: Wake Up World <http://wakeup-world.com/2012/03/07/genetically-modified-food-labeling>
[312] Supra note 9
[313] Supra note 6
[314] Supra note 280

The Regulation provides for the appointment of inspectors and details their powers to enter, carry out tests and inspections, take samples or possession of products, conduct enquiries, require production of information in computerized form in order to investigate or inspect the implementation of the EFSA's decision with respect to approval and labelling of foods containing genetically modified organisms.[315] If the inspector is satisfied that the food or feed containing genetically modified organisms was not being labelled appropriately, he may serve a notice in writing prohibiting the sale of the product in the market. He may also require the product to be removed from the premises and labelled according to the labelling guideline as stated in Regulation 1830/2003. The English Regulation also specifies offences in sections 8, 9, and 10. Section 11 prescribes the penalties for a summary conviction of imprisonment for a term not exceeding three months, or a fine, or both. The Regulations dealing with tracing and labelling requirements for animal feed are similar to the labelling of FDMB.[316]

5.2 (b) The European Court of Justice and genetically modified food

The European Court of Justice (ECJ) is the guardian responsible for interpreting the EU Regulations and it has ruled on the Regulations governing FDMBs sated above. Some of its decisions are detailed below to better understand how the principles underlying the labelling of FDMB are regulated in the EU. The cases highlight how the underlying principles governing FDMB in EU are interpreted by the ECJ.

[315] Supra note 9 At section 5
[316] Supra note 287

Gowan Comércio Internacional e Serviços L v Ministero della Salute[317]

Mandatory labelling requirements are based on the general belief there is a possibility of unintended consequences due to the adoption of GM food and hence precaution is necessary. The ECJ, Court of the Second Chamber in "Gowan Comércio Internacional e Serviços L v Ministero della Salute", decided on the extent to which the precautionary principle and proportionality may be applied in the EU. This case is significant given the fact that labelling of genetically modified foods has to be justified on the basis that it is a provisional precautionary measure adopted proportionate to the risk identified. Even though this case does not specifically deal with the issue of labelling, it is relevant because it has clarified the extent of application of the precautionary principle and proportionality.

The facts of the case are as follows: Gowan acquired DowElanco Europe - a company producing a fungicide called "fenarimol" and pursued its initial application for an authorisation of sale of fenarimol for a period ten years and for an extensive market. Gowan received an initial approval for ten years for unrestricted use. Subsequently, there were reports of endocrine disruption amongst fish due to fenarimol, though there was no scientific certainty. Gowan was informed of this and it amended its application by lowering the time period to seven years and reducing the market coverage. However, the company was informed that its approval was only for eighteen months with very limited market coverage. Gowan, submitted before the Regional Administrative Court of law in Italy that the restrictions on permitted use and reduction of the time period were

[317] ECJ, Gowan Comércio Internacional e Serviços L v Ministero della Salute, C-77/09,[2009] EUR-Lex, < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62009CJ0077:EN:HTML> at 16

unjustified on the basis of the initial assessment procedure. The matter was referred to the ECJ. The EC stated that there was a study indicating an impact on the endocrine systems on fish. The study was conducted by Council of Agricultural Ministries; however, the Council of Agricultural Ministries had not made any definitive decision about safe use.[318] Italy had enacted two directives based on the study, which ultimately led to the reduction in the time period as well as permitted use of fenarimol.

The ECJ, dismissed the objections of Gowan and held that the effects fell under the assessments of harmful effects on human and animal health. The ECJ held that the commission must be allowed a wide discretion in appraising complex scientific assessments. In dealing with the scope of the precautionary principle the it stated that there was some scientific uncertainty regarding the assessment of the effects on the endocrine system.[319] The ECJ also examined the work of the Standing Committee of the Council of Agricultural Ministries and the EC and held that the EC had not erred in applying the precautionary principle, even though no definitive decision of impact on health was made at the Council of Agricultural Ministries.

The ECJ explained that since precautionary principle is an integral part of the decision making process leading to the adoption of measures to protect human and animal health and environment it could also find application within pre-market approval system. This appears to be the first time the precautionary principle has been expressly recognized as a

---

[318] Ibid at 38
[319] Ibid at 73

risk management instrument.[320] With respect to proportionality the Court concluded that given the concerns on the subject the measures restricting the use of fenarimol was suitable for achieving the purpose of the objective. The ECJ held that there was no outright ban and that the Company could apply for renewal and hence found the measures proportional.[321]

As a result of this analysis the ECJ seems to have lowered the evidentiary threshold that warrants precautionary action. All that the Court considered sufficient in this cases was identified scientific uncertainty on the basis of which it upheld the Italian directive.[322]

Monsanto SAS v Ministre de l'Agriculture et de la Peche[323]

This is another landmark decision, the ECJ nullified the French ban on a GM crop – MON 810. Between 2007 and 2008 France adopted a series of decrees that banned the sale, use and cultivation of MON 810 maize. MON 810 maize was authorised for use as seeds for the purpose of planting and was notified as an existing product in accordance with the conditions set out in Article 20 of Regulation 1829/2003[324](dealing with status of existing products). The maize was subsequently a subject of a pending application for renewal of authorization. The ECJ held that under such circumstances the genetically modified organism may not have their use or sale suspended.

---

[320] Alemanno, "The shaping of European Regulation by Community Courts", Jean Monnet Working Paper 18/2008, online; (2008) page 46 < http://papers.ssrn.com/sol3/papers.cfm>
[321] Surap note 317 at 84
[322] Supra note 320
[323] ECJ, Monsanto SAS v Ministre de l'Agriculture et de la Peche, Cases C-58/10 to C-68/10, [2010], EUR-Lex, < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62010CJ0058:EN:HTML
[324] Supra note 5 Art 20

The ECJ also considered the 'Emergency Measures' clause in Article 34 of Regulation 1829/2003.[325] It stated that Member States have to establish the existence of a clear and serious risk to human, animal or environmental health along with the emergency in order to be justified under this article. The court stated that the expressions "likely" and "serious" risk must be understood as referring to a significant risk that clearly jeopardises human, animal or environment. That risk must be established on the basis of new scientific evidence. That would justify member countries adopting emergency measures.

Finally, the ECJ held that in light of the overall scheme adopted in Regulation 1829/2003, the ultimate responsibility lies with the EC and the Council of Agricultural Ministries to determine the safety and adoption of GM food. The court held that France was not able to justify its ban and invalidated its moratorium as

> "purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified. On the contrary, such protective measures, notwithstanding their temporary character and even if they are preventive in nature, may be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, which indicate that those measures are necessary."[326]

This case is of significance given Italy's approach to approving genetically modified crops within its national boundaries. It also indicates the extent of centralised control within the European Union on approval and marketing of genetically modified organisms.

---

[325] Supra note 5 at Art 34
[326] Supra note 323 para 77

Karl Heinz Bablock and Others v Freistaat Bayern[327]

This is another landmark judgement the Grand Chamber of the European Court of Justice, which considered the impact of unintentional and adventitious presence of genetically modified ingredients in honey. Pollen from genetically modified plants which were no longer capable of re-producing was found in honey from an apiary which was located about 500m from a field in which MON 810 Maize was being grown on an experimental basis . The court considered the following questions:

- Does the pollen constitute a genetically modified organism according Regulation 1829/2003?
- What is the scope of Article 2.10 of Regulation 1829/2003?
- Whether the labelling threshold would apply as an analogy to articles 3(1) and 4(1) of Regulation 1829/2003 dealing with presence of unauthorised genetically modified ingredients in food?[328]

The facts of the case are as follows: In 1998 Monsanto Europe obtained authorization to place genetically modified 810 maize on the market. The cultivation of this maize was prohibited in Germany and placed under provisional suspension. Freistaat Bayern owned various plots of land on which MON 810 maize was being cultivated for research purposes. About 500 meters from him Mr. Bablok, an amateur bee keeper produced both honey and pollen for sale. In 2005, the DNA of MON810 maize was detected in the maize pollen harvested by Mr. Bablock. The Bavarian Administrative Court held that the apicultural products in question are no longer marketable or fit for consumption as they had been subjected to a "material interference". The court further explained the meaning of "material interference" with the product. It stated that contamination by pollen from

[327] Supra note 37
[328] Supra note 37 at para 53

MON 810 strain of maize made the product GM food and hence required authorization by article 4(2) of Regulation 1829/2003 and be labelled as GM prior to being placed in the market. The court also held that the pollen from the maize was an organism within the meaning of article 4.2 of Regulation 1829/2003, even though it had lost its inability to replicate itself, it could still act as a male gamete under natural conditions and transfer material to female gametes and hence was a GMO[329]

The ECJ considered the above three questions and held that the pollen did not constitute a GMO within the article 2.4 of Regulation 1829/2003. It stated that as the pollen had lost its ability to reproduce and was totally incapable of transferring its genetic material it would not come under the definition of GMO in Regulation 1829/2003.

To the second question the ECJ held that article 2.1, 2.10, 2.13 and article 1(c) of Regulation 1829/2003 established the general principles and requirements of food law. The Grand Chamber held that that products such as honey and food supplements constitute 'food' under Article 2.1 of Regulation 1829/2003, because they were produced from MON 810 maize flowers which contained GMOs. The ECJ held that despite the fact that pollen was not considered a GMO, honey was considered as food containing ingredients produced from genetically modified organisms as it was produced from the MON810 Maize flowers (process of production involved GMOs). The Court held that this classification may be made irrespective of whether contamination of the substance in question was intentional or unintentional.

---

[329] Supra note 37 at para 28 to 52

To the third question the ECJ held that article 3(1) and 4(2) must be interpreted as having an implied obligation to authorise and supervise food stuff. Article 4(2) required specific authorisation before food containing genetically modified organisms could be placed in the market. The ECJ held that the threshold of 0.9% that was permitted for labelling could not be applied by an analogy to such an obligation to authorize and supervise. This indicates that there is a zero tolerance for the presence of unauthorised GMOs in food, even though such presence was accidental. Thus any GMO has to approved by the EFSA before it can be placed in the market and the threshold level is not applicable to an unapproved GMO. This case has far reaching significance as it laid down that the presence of GMOs whether intentional or unintentional would need to be approved and labelled according to the EU regulations.

5.3 Voluntary Model and its adoption in Canada:

The voluntary model of labelling permits food producers to choose whether to label their products as containing GM ingredients or not. The voluntary labelling regulations determine the framework of what will constitute GM or non GM, how a label regarding the presence or absence of GM contents need to be indicated if producers choose to label their products. The voluntary model has been generally adopted in countries where there is widespread acceptance of GM food. US and Canada are amongst the leading producers

of FDMB and consider the food to be safe as it is approved on the basis of the principle of substantial equivalence.[330]

Health Canada and the Canadian Food Inspections agency (CFIA) are the two agencies of the government that share the responsibility of approving labelling and implementing the policies regarding GM food. Health Canada's responsibility for food labelling falls within the department's mandate to safeguard health and safety while the CFIA leads the Federal program to develop general food labelling policies and regulations.[331] As stated on its website the "CFIA is responsible for protecting consumers from mis-leading labels and fraud with respect to food labelling, packaging and advertising."[332]

The Health Canada defines GM food as,

> food derived from an organism that has had some of its heritable traits changed. This can involve:
>
> - Traditional breeding techniques of crossbreeding.
> - Using chemicals or radiation to alter the genetic make-up of the organism's cells in a process called mutagenesis.
> - Applying recombinant DNA or genetic engineering techniques - for instance, introducing a gene from one species into another species.[333]

This definition includes both traditional breeding techniques and biotechnology techniques. So any new food would come under the purview of Health Canada if its genetic makeup has been altered. Such GM food is termed as "Novel Foods" in Canada.

The Canada Food and Drugs Act[334] and its Regulations govern the adoption of Novel

---

[330] Supra note 45
[331] Labelling of Genetically Engineered Foods in Canada, (10 May 2012), online: Canadian Food inspection Agency <http://www.inspection.gc.ca/food/labelling/other-requirements/method-of-production/ge-factsheet/eng/1333373177199/1333373638071>
[332] Ibid
[333] The Regulation of Genetically Modified Foods, (28 Nov 2005), online: Health Canada < http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php>

Foods in Canada. The manufacturer or importer of the Novel food who wishes to sell or advertise the food in Canada, must submit an application to Health Canada for a pre-market safety assessment, as per the provisions of Division 28 of Part B of the Food and Drugs Regulations[335] also known as Novel Food Regulation.

Detailed information about the food products, testing, development and qualities of the food has to be supplied to Health Canada on their guidelines. Health Canada reviews the application by conducting a full safety assessment of the product which involves a rigorous scientific assessment by Health Canada's evaluators. Once the evaluation of the product is complete, a proposal is prepared which is further reviewed by senior members in the Food Directorate and a decision is made on approving or dis-approving the product.[336]

The pre-market safety assessment of genetically modified food is based on the "Principle of Substantial Equivalence."[337] Application of the concept is not a safety assessment per se, but helps to identify similarities and differences between the existing food and the new product. The new food is also subject to further toxicological investigation. Substantial equivalence is a starting point in the safety evaluation, rather than an endpoint of the assessment.[338]

If the product is approved, at this stage other regulatory approvals for environment and

---

[334] Supra note 10
[335] Food and Drug Regulations, C.R.C., c. 870 Division 28
[336] Supra note 333
[337] Supra note 45
[338] Kuiper HA, Kleter GA, Noteborn HP, Kok EJ., "Assessment of the food safety issues related to genetically modified foods", online: (2001) 27:6 The Plant Journal for cell and molecular biology http://www.ncbi.nlm.nih.gov/pubmed/11576435

feed safety is sought. Subsequent to the approval on all fronts, a letter of no-objection is sent to the product developer by Health Canada. This letter could outline any restriction or requirement as deemed necessary. It is here that any notification for labelling will be made.

The mandatory labelling adopted in the EU is based on the fundamental belief that the consumer has a right to know, what is in his food. There is however, no such corresponding statutory right in Canada. While Article 19, of the Universal Declaration of Human Rights[339] speaks of a broad right to information, it has been adopted to a limited extent in Article 2 of the Canadian Charter..[340]

.

The changes in global climate have brought to the forefront the link between Human Rights and Environment. In 1994, a "Declaration of Principles on Human Rights and the Environment", was proposed.[341] Although no draft was not adopted could such a declaration require mandatory labelling of FDMB? Even though it may be argued that consumers are not sure of the long term effects of consumption of FDMB, there has been no identifiable definite risk caused due to the adoption and consumption of FDMBs.

---

[339] Universal Declaration of Human Rights, 10 December 1948, U.N. Doc. A/810 at 71 provides a right to "..seek, receive and impart information and ideas.."

[340] Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982 being Schedule B to the Canada Act 1982 (U.K.), 1982, c. 11. at s 2 states that everyone has the freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication. This section is limited by s 1 of the Charter which states that this freedom may be restricted so long as the restriction is justified and reasonable. The Supreme Court of Canada reviewed the extent of limitation on this freedom in Irwin Toy v. Quebec and held that the government can limit the freedom of expression so long as the restrictions are designed to protect individuals and society as a whole.

[341] Donald K. Anton & Dinah L. Shelton, "Problems in Environmental Protection and Human Rights: A Human Right to the Environment", online: (2011), ANU College of Law Research Paper No. 11-17, Social science research Network, <http://papers.ssrn.com/sol3/papers.cfm> the draft proposed that "All persons have the right to safe and healthy food and water adequate to their wellbeing."

FDMB are approved based on extensive scientific testing and are considered safe. Countries with voluntary labelling treat it as unfair trade practise to require labelling.[342] Given these considerations it might be difficult to substantiate that consumers have a legal "right to know" when there is no law that states that they do.

The problem of labelling genetically modified foods without misleading the consumers, has been a preliminary reason for supporting a voluntary model of labelling. Biotechnology involves the use of complex technologies and it is difficult to reduce that information clearly and truthfully in a label. In the event of a future dispute demanding information to support one's right to expression, the inability to clearly and truthfully disseminate information about complex technologies involved in genetically modified foods, could be used as a reason to favour a voluntary model of labelling and thereby limit the freedom of expression in the Canadian Charter.

The voluntary labelling model adopted in Canada is regulated and monitored by Health Canada. It requires labelling in the event of presence of allergens, sulphites or changes in nutrition components. Health Canada states:

> Currently in Canada, labelling is mandatory if there is a health or safety issue with a food. For example, if the nutritional value or composition of the food has been changed, or if there is an allergen present in the food, the food must be labelled as such. In this situation, special labelling is required to alert consumers or susceptible groups in the population. This applies to all foods, including GM foods.[343]

---

[342] Colette Douglas "Time that Goliath ate humble pie" (4 August 2000), online: The Daily Mail , as quoted in Krishna, P. & Perry, M.,"Making Sense of Mouse Tales: Canadian Lifeform Patents Topsy-Turvy" online: (2001) 23.4 European Intellectual Property Review <http://westlawcanada.com>

[343] Supra note 333

The above quote indicates a restricted voluntary labelling model being adopted in Canada. The above restriction; however, are applicable to all food types whether GM or not and hence there is no particular restriction applicable only to GM foods.

Biotechnology today has opened the doors for increased and enhanced production of food through a variety of scientific tools and techniques. According to the CFIA there have been three major consultations since 1993 in Canada on labelling of foods derived from genetic engineering or modern bio-technology. A set of guidelines were developed based on the below mentioned consensus:

- Require mandatory labelling if there is a health or safety concern, i.e., from allergens or a significant nutrient or compositional change (these decisions will be made by Health Canada), in order to inform consumers of the allergen or change
- Ensure labelling is understandable, truthful and not misleading
- Permit voluntary positive labelling on the condition that the claim is not misleading or deceptive and the claim itself is factual
- Permit voluntary negative labelling on the condition that the claim is not misleading or deceptive and the claim itself is factual.[344]

The underlying principle for labelling of GM foods is "Food products derived from genetic modification that are demonstrated to be safe and nutritious, are treated the same as non-genetically modified foods with regard to labelling requirements".[345]

The voluntary labelling in Canada is based on the below two legislation and a guideline

(a) The Food and Drugs Act and the Food and Drug Regulations[346]

(b) The Consumer Packaging and Labelling Act[347]

---

[344] Supra note 331
[345] Frequently asked questions – Biotechnology and genetically modified foods, Food and Nutrition (19 June 2006), online: Health Canada< www. hc-sc.gc.ca>
[346] Supra note 10

(c) Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering.[348]

5.3 (a) Food and Drugs Act

Section 5 and 6 of the Food and Drugs Act deals to a limited extent with labelling of food in general. Section 5 states The Food and Drugs Act prescribes standards with labelling and packaging and states:

> (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.
> (2) An article of food that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1)[349]

This section requires labelling of all food including GM foods to be labelled in a truthful manner without any mis-representation regarding its character, composition, safety, etc. Further section 6 refers the same standard to be met with foods that are imported into Canada or that has been sent from one province in to another.

Division 28 of the Food and Drug Regulations[350] deals with Novel Foods. It elaborates the definitions of "genetically modified' and "novel foods". It also states the procedure for securing the approval from Health Canada with respect to safety. It requires all information with respect to the method by which the novel food is manufactured,

---

[347] Supra note 11
[348] Supra note 12
[349] Supra note 10 at s 5
[350] Supra note 335

prepared, preserved, packaged and stored, details of the change, information on intended use, information on history of use if available, text of labels to be used and the grounds on which safe use is claimed. Health Canada has 45 days to review such application.[351] The Director could ask for additional information in which case an additional 90 days is provided for review of information. After such a review a notice of acceptance or rejection is given in writing.

Health Canada has developed "Guidelines for Safety Assessment of Novel food" which is use to determine the safety of novel foods. This safety assessment process is based on

> principles developed through international expert consultations carried out by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations, the Codex Alimentarius Commission and the Organisation for Economic Co-operation and Development (OECD).[352]

The scientific assessment of novel foods is based on scientific principles adopted by CAC. Thus Health Canada has incorporated the CAC standards in it approval and regulation of FDMB. As the texts in the Compilation were adopted prior to the adoption of the Compilation, Canada has its policies for approval of FDMB in accordance with the Compilation.

Canada recognises the rapid development in biotechnology and has made effects to update scientific assessments with the advances in technology.[353] In 1999, Canada setup 'Canadian Biotechnology Advisory Committee' that consists of experts from various

---

[351] Supra note 335 at S B.28.002(1)(e)
[352] Supra note 345
[353] Supra note 345

disciplines and public. It provides advice on biotechnology with respect to ethical, social, regulatory, economic and environmental and health issues. As an independent committee it is tasked with proving neutral advice to federal departments and updating federal departments with advances in biotechnology.[354]

5.3 (b) Consumer Packaging and Labelling Act

The Consumer Packaging and Labelling Act[355] provides a uniform standard for labelling all consumer goods. Section 2 of this act defines "label to be any mark, sign, device, imprint, stamp, brand, ticket or tag"[356]. Section 10[357] states that each label should contain a declaration of net quantity, identity and principal place of the producer, identity of the pre-packaged product in terms of its common or generic name or in terms of its function and such information with respect to nature, quality, age, size, material, content, use or method of manufacture or production of the pre-packaged product as may be described. These requirements are in compliance with the Compilation. The Codex General Standard for Labelling of Prepackaged Food[358] prescribes similar conditions for labels in international trade. However, the Consumer Packaging and Labelling Act also requires producers to indicate content or method of production in terms of its common or generic function or name and this could prove very challenging for bio-technology techniques.

The Consumer Packaging and Labelling Act also provides for appointment of inspectors

---

[354] Canada's Biotechnology Strategy (2005 December 06), online: Health Canada < http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg>
[355] Supra note 10
[356] Supra note 11 at s 2
[357] Supra note 11 at s 10
[358] Supra note 179

under section 13 to enforce these provisions. The 2012 Canadian Budget states:

> The Government will change how the Canadian Food Inspection Agency (CFIA) monitors and enforces non-health and non-safety food labelling regulations. The CFIA will introduce a web-based label verification tool that encourages consumers to bring validated concerns directly to companies and associations for resolution.[359]

With GM not considered as a safety issue, cutting costs for enforcement of consumer labelling, monitoring positive or negative labelling of genetically modified ingredients in food would prove even more challenging. This exacerbates the already complicated task of verifying any labelling that is being used by producers. The Consumer Packaging and Labelling Act prescribes a punishment in section 20(1)[360] of a fine not exceeding $50,000 or imprisonment up to six months or both in a summary conviction and for a conviction on indictment a fine not exceeding $250,000 or imprisonment of a term up to 2 years or both. The section also provides for criminal liability of officers of corporations. It prescribes a limitation period of two years.

5.3 (c) National Standard on voluntary labelling and advertising of foods that are and are not products of genetic engineering.

The last guideline that forms the foundation of all labelling of FDMB in Canada is the National Standard on voluntary labelling and advertising of foods that are and are not products of genetic engineering. According to this guideline genetic engineering refers to

---

[359] Budget 2012, (29 March 2012), online: The Government of Canada <http://www.budget.gc.ca/2012/plan/chap5-eng.html>
[360] Supra note 11

> Techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. Examples of the techniques used in genetic engineering include but are not limited to the following:
>
> recombinant DNA (rDNA) techniques that use vector systems techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism cell fusion (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family.[361]

It also defines a label as any legend, word or mark attached to, included in or on, belonging to, or accompanying any food or package containing food. The Act further elaborates the detailed requirements with respect to any claim about the ingredients of food. The preliminary requirement for any claim is that it should be understandable, informative, not false and not misleading. This requirement is similar to the Compilation, the "General Guidelines on Claims"[362] requires that claims should not be mis-leading, should aim to provided consumers information and prohibits claims that cannot be substantiated or that give rise to doubt about the safety of similar food or that could arouse or exploit fear in the consumers.

The guidelines further details, the requirements for both positive and negative labelling. A minimum of 5% of genetically modified content would be required to make a positive claim. Section 5.1 deals with claims about a single ingredient, in order to be eligible under this section more than 95% of the single ingredient food should be produced through genetic engineering. For a multi-ingredient food, the claim would refer to individual ingredients within the food not the food as a whole and it refers to those ingredients that

[361] Supra note 12
[362] Supra note 182

make up 1% or more of the total weight of the food.[363] Information regarding the method of verification, origin of the external genetic material, technique of bio-technology used, reason for the use of bio-technology should be included in a label.[364]

Section 6 deals with negative labels; again the requirement for a negative label is that the percentage of genetically modified content should be less than 5%. The condition being that such genetically engineered ingredients should not have been intentionally added to the food. Thus the food producer should intend to produce the food with 0% of GM content. The accommodation of 5% is provided given Canada's support to the development of genetically engineered food there could be unintended exposure that could lead to mixing of GM ingredients. GM ingredients may inadvertently be included due to "co-mingling as food passes through handling or storage systems, or if wind, insects or animals have spread pollen or seed from one field to another."[365]

The determination of the 5% limit has been considered appropriate for labelling as Canada is amongst the leading producers of genetically engineered food. This standard is periodically reviewed usually once in five years.[366]

Section 7 is an important section that deals with verification systems and testing. Section 7.1 states that verification methods may include and is not limited to testing, detection

---

363 The 5 Percent Allowance in GE Food Labelling, (19 Dec 2011) online: Public Works and government Services Canada <http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/norms-standards/internet/032-0315/fiches-facts/fs01-eng.html>

[364] Supra note 12

[365] Supra note 363

[366] Supra note 363

methods, inspection and audit tracking.[367]

Thus in this model of labelling, labels are

> typically utilised when a manufacturer wishes to distinguish his product from a competing product that consumer may perceive as inferior. The inferiority may be related either to a particular trait such as an ingredient, quality, or to a method of production, such as the use of pesticides. Voluntary labels thus provide an important conduit to consumers because the information conveyed may not be available through other means.[368]

The above quote indicates the difference in purpose of labelling, between the models of labelling. In a mandatory model the purpose is inform the consumers irrespective of whether the labelling will promote the product or not. In a voluntary labelling model; however, the purpose is to inform the consumer with the ultimate intention of distinguishing the product and promoting its sale.

5.4 Mandatory v Voluntary

A comparison of the European model of labelling to the Canadian model, indicates the perceptual differences between the two models of labelling. This difference is bound to continue given the uncertainty in determining the unintended effects of the long term use of genetically modified food. Weighing the pro and cons of each model, merely highlights the indeterminate nature of this problem.

---

[367] Supra note 12 at s 7

[368] Steve Keane, "Can consumers right to know survive the WTO?: The case of food labelling", online: (2006-2007), 16 Transnat'l L. & Contemp. Probs. <http://www.heinonline.org>

While the mandatory label model does provide for post market monitoring of unintended effects, its preliminary objective of informing the consumers has not been fulfilled. The language adopted in Europe has not informed the consumers of the exact nature of the GM content. Labels that indicate whether the food is or is not GM will not adequately assist consumers in differentiating among products, as the reason for genetic modification has also been considered as relevant in determining consumer choice.[369] The insufficiency of the European labelling as a tool to provide such information to consumers was highlighted in the Europeans and Biotechnology survey on 2010.[370] Many are of the opinion that mandatory labelling has only limited the choice of the consumers. It is perceived as a warning to consumers and many have refrained from consuming genetically modified food, as they are not aware of the exact nature of genetic modification and its consequences.[371]

Voluntary labelling on the other hand has not provided any information to consumers. As corporations are not required by law to label their products, producers will not label unless they see a benefit in doing so.[372] This leaves consumers with no information on the basis of which they can choose the type of food they want to consume. The complicated technology used in the process of genetic modification has compounded the problem. The dissemination of any information with respect to the nature and consequences of genetic modification without causing confusion and mistrust in the minds of consumers seems to

---

[369] Supra note 1 at 547
[370] Supra note 277
[371] Guillaume P. Gruère, "Labeling Policies of Genetically Modified food Lessons from an International Review of Existing Approaches", online: (2007) Brief No. 7 International Food Policy Research Institute <https://www.cbd.int/doc/external/mop-04/ifpri-pbs-policy-07-en.pdf>
[372] Supra note 33

be a perennial problem.

The heterogeneous labelling requirement in international trade has affected the costs of food production. The tracing and labelling requirements followed in the EU have increased the cost of productions. As the studies have indicated there is an increase in costs whether significant or marginal will depend on parameters used in the survey.[373] Corporations would be required to adopt segregation and documentation techniques to be able to authenticate food labels. The multitude of differences within the mandatory labelling model has also added to the costs, as different procedures would be adopted based on the threshold levels. In practise, "The mandatory labeling policies in the EU and Japan have resulted in the virtual disappearance of any labelled GM product on the food shelves. These policies encouraged food processors and retailers to avoid using GM ingredients."[374] Hence, producers of FDMB have a restricted market available only in countries supporting biotechnology. They are required to determine their market prior to production of genetically modified food.

The choice between process based or product based labelling is another dimension that has added to the existing problem of dissemination of information. The uncertainty over determination of unintended effects of genetic modification supports the process based labelling model. However, the mere indication that a food product has been produced through genetic modification might not be sufficient information from a consumer's perspective. "It is potentially misleading to only provide for product labels, because, while foods produced with GM materials (e.g., beer fermented using GM yeast) are not necessarily GM

[373] Supra note 258
[374] Supra note 258

themselves, the fact that their production used GM materials is still important to some consumers."[375] Thus it becomes necessary to determine the type of labelling based on the characteristics of the product. This inability to provide for some generalisation has also contributed to the rigid differences amongst countries on the model of labelling to be adopted.

The problem with verification has also been raised as a concern. The testing procedure and the costs of testing has been a factor in determining the threshold level. The variation in verification methods should also be considered prior to determining the threshold level. In addition to different types of genetic modifications, there are different methods of measuring the percentage of GM content.[376] The wide variance in threshold levels between the European Union and Canada indicates the policy choice based on a cost benefit analysis between the cost and efficiency in verification and the ability to use labels that would not misguide consumers.

The complex technology, the lack of certainty of unintended effects, social considerations, variations within the two models of labelling, impact on trade and ability of labels to be ineffective and misleading have all contributed towards the inability to effectively determine the most effective model of labelling. The deliberations at the CAC brought forth all these aspects. The Compilation adopted after nearly two decades of deliberations provides a scientific basis for risk assessment, risk management and risk communication of FDMB. The extent to which these principles will be adopted, implemented and updated to accommodate advances in biotechnology will determine the effectiveness of the Compilation.

---

[375] Supra note 1 at 551
[376] Supra note 1 at 553

Chapter 6: Conclusion

The Labelling of FDMB has been pegged at the intersection of technology, politics, religious, social and ethical beliefs, both at the national and international level. A number of countries have adopted different labelling approaches for FDMB. Implementing a labelling regime involves developing "a set of standards, actions to meet the standards, certification of the actions, and governmental enforcement of the program."[377] The wide variance in acceptance of FDMB has led to a complicated set of requirements that is bound to increase with more countries adopting labelling standards and other countries redefining existing standards.

The development of the standards has been the most controversial part of the process. Based on the negotiations at the CAC, all countries seem to agree on the need to develop some standards for labelling of food derived from modern biotechnology. However, the exact nature of the standard and its implications in international food trade have been issues in which no consensus could be achieved. The adoption of the Compilation last year by the CAC has not altered the issues surrounding labelling of FDMB. The Compilation has; however, provided a more definite standard for evaluation of labelling regimes.

The requirement that the approval and labelling standard should be based on sound

---

[377] Mario F. Teisl and Julie A. Caswell, "Information Policy and Genetically Modified Food: Weighing the Benefits and Costs", Working Paper # 2003-1, online: (2003), University of Massachusetts Amherst-Department of Resource Economics, <http://scholarworks.umass.edu/cgi/viewcontent.cgi?article=1195>

scientific principles was first stated by WTO in its decisions dealing with the approval and sale of FDMB or GM food. The Compilation has reiterated the same requirement. The Compilation acknowledges that each country is free to adopt a model of labelling suitable to its requirement, so long as it is based on scientific principles. As it has recognised labelling as a tool of post market monitoring, the possibility of a blanket challenge before the WTO that mandatory labelling amounts to a restrictive trade practise has been restricted. However, this does not mean that the Compilation would completely protect EU countries or other countries who adopt a mandatory labelling model from being challenged. So long as the country requiring mandatory labelling is able to justify its need for post market monitoring on a perceived risk of scientific certainty, a challenge at the WTO will fail. Otherwise, the fact that such labelling could amount to a restrictive trade practise could be upheld by the WTO.

The preliminary consideration in the event of a challenge could be whether FDMB are considered as "like goods" to their conventional counterparts. The WTO so far has not been clear on this issue. The Compilation has addressed this issue to a marginal extent by declaring that FDMB are not necessarily different merely because of the means of production. The lack of a definite answer only means a potential for possible claims. The complexity in technology and wide possibility of unintended effects forces the issue to be considered on a case by cases basis.

Thus even though the WTO is yet to consider a dispute directly on this issue, a review of existing cases and the Compilation reveals that scientific justification would be the best

ground for defence. The other factors that the WTO could consider are consumer preferences and political considerations. However, as these conditions are variable and indeterminate, it would be hard to depend solely on such factors.

The Compilation; however, has provided countries with a common platform to launch labelling legislation. The reiteration of the requirements in one document would demystify the ambiguity in WTO interpretation. Given the nature of the problem and the ideological differences, providing a common minimum understanding that regulation of FDMB should be based on scientific evidence, is a definite step forward towards harmonisation of international labelling requirements. Progress in this direction would help promote international food trade and thus help achieve the purpose of the CAC.

At the national level however, a review of the current implementation of labelling standards reveals that, labelling has not been able to address the problem it sought to remedy. Neither model of labelling has been able to deliver the necessary information to consumers or provide consumers a choice.[378] The mandatory model that uses simple labels to inform consumers have not been very successful as the information has been in-sufficient to impact consumer choice. The labels have acted as a warning and have forced stores that used to sell FDMB to move away and switch to non-GM sources. This has impacted the choice available to consumers in such markets. In the voluntary labelling markets, companies do not label as they believe that costs will increase or they are unable to reduce the information to a simple label without misleading consumers. The belief that

[378] Supra note 371

consumers may not favour GM ingredients or the fact that other companies might not follow due to the lack of labelling requirements and hence could lead to a loss in business has prevent corporations from labelling. This has led to a lack of information to consumers and has restricted their choice as many are not aware of what they are consuming. Thus neither model of labelling has provided consumers sufficient information to enable consumer choice.

The other problem at the national level that has now started gaining momentum in the EU is the determination of threshold levels for negative labelling. Some countries such as Canada have adopted one threshold; others however, feel the need to determine a separate threshold for negative labelling. The recent adoption of standards in France and the demand in United Kingdom[379] to follow, indicates that another storm could be brewing. The Compilation has not considered this aspect and has left it to the national governments to decide. If the threshold for negative labelling varies from country to country it would clearly add to the existing heterogeneity and complexity.

The issue of whether labelling should be product based or process based is again another aspect in which there can be no safe generalisation. Some examples that indicate the perplexities involved are as follows:

> a single gene engineered into a tomato could hypothetically represent 1% of the proteins expressed by the tomato plant. Does that fact make the entire tomato GM? On the other hand, a beer produced using GM yeast could result in a finished product with no GM protein content at all. Is that beer non-

[379] Caroline Lucas, "The UK needs a labelling scheme for GM-free meat products", the Guardian UK (10 February 2011), online: The Guardian <http://www.guardian.co.uk/environment/blog/2011/feb/10/labelling-gm-meat>

> GM? Citrus are routinely grown using rootstock. The root of the plant is from one variety, while most of the trunk and all of the branches are from another variety. If the root is GM but the branches are not, are the oranges GM?[380]

The labelling of the above products will depend on whether a country adopts a product or a process labelling. Some countries such as the EU have both process and product based labelling. Such an approach might be the safest as it would cover all foods exposed to or containing GM ingredients. However, even with the adoption of both product and process, the earlier problems of informing the consumers would still not be addressed.

Thus labelling of FDMB is a multi-dimensional problem which cannot be addressed by a single strategy. Until science provides more definitive answers we might be stuck with a multitude of conflicting requirements. The very nature of food and the fast pace of the technology involved makes generalisation almost unproductive. More needs to be done to educate consumers. The consumer information strategies (other than labelling) adopted in the EU could be an example. The most suitable method for the co-existence of FDMB and protection of consumer interests would be to educate consumers about the regulatory process and the extensive scientific tests undertaken prior to release of the FDMB into the market. The recent approval in Canada of "Genuity SmartStax" containing eight genetically modified traits without any public disclosure about how it was approved[381] is not a method that would get consumer support and loyalty. Further, integrative testing should be adopted in which all aspects of FDMB are considered simultaneously. Such

---

[380] Supra note 1 at 554

[381] Mark Perry, "Genetically Modified Organisms: Why we need transparent system of regulation", online: (2010), SSRN –id 1533657, SSRN < http://papers.ssrn.com/sol3/papers.cfm>

testing should be adopted in a transparent manner.[382] The Canadian Biotechnology Advisory Committee, that has been tasked with providing information to the public, needs needs to increase its efforts to make unbiased information more accessible to consumers. Increased access to information would help build confidence in biotechnology development and would channel the growth of biotechnology to the needs of consumers.

Investing in unbiased consumer education and approaching FDMB with extensive integrated testing would help achieve and sustain consumer support for FDBM. Labelling of FDMB could be considered subsequent to extensive education. Only if consumers are aware of the exact nature of genetic modification will they be able to make an informed choice and in such an educated market, producers would also be willing to adopt labelling.

[382] Ibid

Appendix I

Procedures for the Elaboration of Codex Standards and Related Texts

Note: Throughout this text the word "Standard" is meant to include any of the recommendations of the Commission intended to be submitted to Governments for acceptance. Except for provisions relating to acceptance, the Procedures apply mutatis mutandis to codes of practice and other texts of an advisory nature.

1. The full procedure for the elaboration of Codex standards is as follows. The Commission decides, taking into account the "Criteria for the Establishment of Work Priorities", that a standard should be elaborated and also which subsidiary body or other body should undertake the work. Decisions to elaborate standards may also be taken by subsidiary bodies of the Commission in accordance with the above-mentioned criteria subject to subsequent approval by the Commission or its Executive Committee at the earliest possible opportunity. The Secretariat arranges for the preparation of a "proposed draft standard" which is circulated to governments for comments and is then considered in the light of these by the subsidiary body concerned which may present the text to the Commission as a "draft standard". If the Commission adopts the "draft standard" it is sent to governments for further comments and in the light of these and after further consideration by the subsidiary body concerned, the Commission reconsiders the draft and may adopt it as a "Codex standard". The procedure is described in Part 1 of this document.

2. The Commission or the Executive Committee, or any subsidiary body, subject to the confirmation of the Commission or the Executive Committee may decide that the urgency of elaborating a Codex standard is such that an accelerated elaboration procedure should be followed. While taking this decision, all appropriate matters shall be taken into consideration, including the likelihood of new scientific information becoming available in the immediate future. The accelerated elaboration procedure is described in Part 2 of this document.

3. The Commission or the subsidiary body or other body concerned may decide that the draft be returned for further work at any appropriate previous Step in the Procedure. The Commission may also decide that the draft be held at Step 8.

4. The Commission may authorize, on the basis of two-thirds majority of votes cast, the omission of Steps 6 and 7, where such an omission is recommended by the Codex Committee entrusted with the elaboration of the draft. Recommendations to omit steps shall be notified to Members and interested international organizations as soon as possible after the session of the Codex Committee concerned. When formulating recommendations to omit Steps 6 and 7, Codex Committees shall take all appropriate matters into consideration, including the need for urgency, and the likelihood of new scientific information becoming available in the immediate future.

5. The Commission may at any stage in the elaboration of a standard entrust any of the

remaining Steps to a Codex Committee or other body different from that to which it was previously entrusted.

6. It will be for the Commission itself to keep under review the revision of "Codex standards". The procedure for revision should, mutatis mutandis, be that laid down for the elaboration of Codex standards, except that the Commission may decide to omit any other step or steps of that Procedure where, in its opinion, an amendment proposed by a Codex Committee is either of an editorial nature or of a substantive nature but consequential to provisions in similar standards adopted by the Commission at Step 8.

7. Codex standards are published and governments are invited to notify the Commission's Secretariat of the status or use of the Codex standard in accordance with their established legal and administrative procedures. They are also sent to international organizations to which competence in the matter has been transferred by their Member States. See Part 3 of this document. Details of notifications are published periodically by the Commission's Secretariat.

PART 1: UNIFORM PROCEDURE FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

Steps 1, 2 and 3

(1) The Commission decides, taking into account the "Criteria for the Establishment of Work Priorities", to elaborate a World-wide Codex Standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a World-wide Codex Standard may also be taken by subsidiary bodies of the Commission in accordance with the above mentioned criteria, subject to subsequent approval by the Commission or its Executive Committee at the earliest possible opportunity. In the case of Codex Regional Standards, the Commission shall base its decision on the proposal of the majority of Members belonging to a given region or group of countries submitted at a session of the Codex Alimentarius Commission.

(2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).

(3) The proposed draft standard is sent to Members of the Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests.

Step 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed

draft standard.

Step 5
The proposed draft standard is submitted through the Secretariat to the Commission or to the Executive Committee with a view to its adoption as a draft standard. (Without prejudice to any decision that may be taken by the Commission at Step 5, the proposed draft standard may be sent by the Secretariat for government comments prior to its consideration at Step 5, when, in the opinion of the subsidiary body or other body concerned, the time between the relevant session of the Commission and the subsequent session of the subsidiary body or other body concerned requires such action in order to advance the work). In taking any decision at this step, the Commission or the Executive Committee will give due consideration to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests. In the case of Regional Standards, all Members of the Commission may present their comments, take part in the debate and propose amendments, but only the majority of the Members of the region or group of countries concerned attending the session can decide to amend or adopt the draft. In taking any decisions at this step, the Members of the region or group of countries concerned will give due consideration to any comments that may be submitted by any of the Members of the Commission regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

Step 6
The draft standard is sent by the Secretariat to all Members and interested international organizations for comment on all aspects, including possible implications of the draft standard for their economic interests.

Step 7
The comments received are sent by the Secretariat to the subsidiary body or other body concerned, which has the power to consider such comments and amend the draft standard.

Step 8
The draft standard is submitted through the Secretariat to the Commission together with any written proposals received from Members and interested international organizations for amendments at Step 8 with a view to its adoption as a Codex standard. In the case of Regional standards, all Members and interested international organizations may present their comments, take part in the debate and propose amendments but only the majority of Members of the region or group of countries concerned attending the session can decide to amend and adopt the draft.

Appendix II

Rule XI of the Rules of Procedure of the Codex Alimentarius Commission:

1. The Commission may establish the following types of subsidiary bodies:

(a) subsidiary bodies which it deems necessary for the accomplishment of its work in the finalization of draft standards;
(b) subsidiary bodies in the form of:
(i) Codex Committees for the preparation of draft standards for submission to the Commission, whether intended for worldwide use, for a given region or for a group of countries specifically enumerated by the Commission.
(ii) Coordinating Committees for regions or groups of countries which shall exercise general coordination in the preparation of standards relating to such regions or groups of countries and such other functions as may be entrusted to them.

2. Subject to paragraph 3 below, membership in these subsidiary bodies shall consist, as may be determined by the Commission, either of such Members of the Commission as have notified the Directors-General of FAO or WHO of their desire to be considered as Members thereof, or of selected Members designated by the Commission.
3. Membership of subsidiary bodies established under Rule XI.1(b)(i) for the preparation of draft standards intended primarily for a region or group of countries, shall be open only to Members of the Commission belonging to such a region or group of countries.

4. Representatives of members of subsidiary bodies shall, insofar as possible, serve in a continuing capacity and shall be specialists active in the fields of the respective subsidiary bodies.

5. Subsidiary bodies may only be established by the Commission except where otherwise provided in these Rules. Their terms of reference and reporting procedures shall be determined by the Commission.

6. Sessions of subsidiary bodies shall be convened by the DirectorsGeneral of FAO and WHO:
(a) in the case of bodies established under Rule XI.1(a), in consultation with the Chairperson of the Commission;
(b) in the case of bodies established under Rule XI.1(b)(i) (Codex Committees), in consultation with the chairperson of the respective Codex Committee and also, in the case of Codex Committees for the preparation of draft standards for a given region or group of countries, with the Coordinator, if a Coordinator has been appointed for the region or group of countries concerned;
(c) in the case of bodies established under Rule XI.1(b)(ii) (Coordinating Committees), in consultation with the Chairperson of the Coordinating Committee.

7. The Directors-General of FAO and WHO shall determine the place of meeting of

bodies established under Rule XI.1(a) and Rule XI.1(b)(ii) after consultation, where appropriate, with the host country concerned and, in the case of bodies established under Rule XI.1(b)(ii), after consultation with the Coordinator for the region or group of countries concerned, if any.

8. Notice of the date and place of each session of bodies established under Rule XI.1(a) shall be communicated to all Members of the Commission at least two months before the session.

9. The establishment of subsidiary bodies under Rule XI.1(a) and Rule XI.1(b)(ii) shall be subject to the availability of the necessary funds, as shall the establishment of subsidiary bodies under Rule XI.1(b)(i) when any of their expenses are proposed to be recognized as operating expenses within the budget of the Commission in accordance with Article 10 of the Statutes of the Commission. Before taking any decision involving expenditure in connection with the establishment of such subsidiary bodies, the Commission shall have before it a report from the Director-General of FAO and/or WHO, as appropriate, on the administrative and financial implications thereof.

10. The Members who shall be responsible for appointing Chairpersons of subsidiary bodies established under Rule XI.1(b)(i) shall be designated at each session by the Commission and shall be eligible for re-designation. All other officers of subsidiary bodies shall be elected by the body concerned and shall be eligible for re-election.

11. The Rules of Procedure of the Commission shall apply mutatis mutandis to its subsidiary bodies."

Appendix III

Compilation of Codex Texts Relevant to Labelling of Food Derived from Modern Biotechnology *

CAC/GL 76-2011

1. PURPOSE

The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.

2. CONSIDERATIONS

Different approaches regarding labelling of foods derived from modern biotechnology are used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.

3. COMPILATION OF RELEVANT CODEX TEXTS

3.1 General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985); and particularly, Sections 3.1, 3.2, 4.1.1, 4.1.2, 4.2.2, 7.1

3.2 General Guidelines on Claims (CAC/GL 1-1979); and particularly, Sections 1.2, 1.3, Section 2 – Definition of Claim, 3.3, 3.5, 4.1, 5.1 (iii), 5.1 (iv), 5.1 (v), 5.1 (vi)

3.3 Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997); Introduction and particularly, Sections 1.1, 1.2, 1.3, 1.4 y 1.5

3.4 Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999); and particularly Section1.5

3.5 General Guidelines for Use of the Term "Halal" (CAC/GL 24-1997)

3.6 Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

3.7 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003); and particularly, Paragraph 19

3.8 Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)

3.9 Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms (CAC/GL 46-2003)

3.10 Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)

* For a definition of the term "modern biotechnology" see the Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 44-2003)

Bibliography

A Statutes / Treaties / International Agreements / International Guidelines

International Agreements and Treaties:

Charter of United Nations, 26 June 1945, Can TS 1945 No 7, online: United Nations<http://www.un.org/en/documents/charter/index.shtml>

Constitution of the Food and Agricultural Organisation, Can TS 1945 No 32, online: FAO <http://www.fao.org/docrep/x5584e/x5584e00.htm#Contents>

Constitution of the World Health Organisation, UN TS 1946 No14, online: Yale Law School,<http://avalon.law.yale.edu/20th_century/decad051.asp>

Convention on Biological Diversity, " Cartagena Protocol on Biosafety", (adopted on 29 January 2000) < https://bch.cbd.int/protocol/text/>

Convention on Biological Diversity, " Cartagena Protocol on Biosafety", (adopted on 29 January 2000) < https://bch.cbd.int/protocol/text/>

General Agreement on Tariffs and Trade 1994, Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 187

Marrakesh Agreement Establishing the World Trade Organization, Agreement on Technical Barriers to Trade, 15 April 1994, 1867 U.N.T.S. 493 http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

Marrakesh Agreement Establishing the World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures,15 April 1994, 1867 U.N.T.S. 493 http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

Universal Declaration of Human Rights , 10 December 1948, U.N. Doc. A/810 at 71

World Trade Organisation, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 15 April 1994, 1867 U.N.T.S. 14

International Guidelines:

"Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology", Codex Alimentarius Commission , 2011, CAC/GL76-2011 < http://www.codexalimentarius.org/standards/list-of-standards/en/>

"General Guidelines on Claims", The Codex Alimentarius Commission, (1979), CAC/GL 1-1979, <http://www.codexalimentarius.org/standards/list-of-standards/en/>

"General Principles of the Codex Alimentarius" , FAO, online FAO Corporate Document Repository http://www.fao.org/DOCREP/005/Y2200E/y2200e05.htm

"Guideline for the conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals" (2008), The Codex Alimentarius Commission, CAC/GL 68-2008, <http://www.codexalimentarius.org/standards/list-of-standards/en/>

"Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms" (2003), The Codex Alimentarius Commission, (2003) , CAC/GL 46-2003, <http://www.codexalimentarius.org/standards/list-of-standards/en/>

"Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants" (2003), The Codex Alimentarius Commission, (2003), CAC/GL 45-2003, <http://www.codexalimentarius.org/standards/list-of-standards/en/>

"Guidelines for the use of Nutrition and Health Claims ", The Codex Alimentarius Commission, (1997), CAC/GL 23-1997, <http://www.codexalimentarius.org/standards/list-of-standards/en/>

"Measures to Facilitate Consensus", (adopted in 2003) Codex Alimentarius Commission Procedural Mannual, 20th Ed., Codex Alimentarius Commission, <http://www.codexalimentarius.org/procedures-strategies/procedural-manual/en/>

"Principles for the Risk Analysis of Foods Derived from Modern Biotechnology", The Codex Alimentarius Commission, (2003), CAC/GL 44-2003 <http://www.codexalimentarius.org/standards/list-of-standards/en/>

"Rules Of Procedure of the Codex Alimentarius Commission", (adopted in 1961) Codex Alimentarius Commission Procedural Mannual, 20th Ed., Codex Alimentarius Commission, http://www.codexalimentarius.org/procedures-strategies/procedural-manual/en/

"Working Principles for Risk Analysis for Food Safety for Application by Governments", The Codex Alimentarius Commission, (2007) , CAC/GL 62-2007,

<http://www.codexalimentarius.org/standards/list-of-standards/en/>

Codex Alimentarius Commission Procedural Manual 20th Ed., online: (2011), Secretariat of the Codex Alimentarius Commission, <www.codexalimentarius.net> at 213

Codex General standard for labelling of Pre-packaged Food Codex General standard for labelling of Pre-packaged Food, The Codex Alimentarius Commission, 1985, Codex-Stan 1-1985, http://www.codexalimentarius.org/standards/list-of-standards/en/

General Guidelines for Use of the term "Halal", The Codex Alimentraius Commission, (1997), CAC/GL 24-1997; <http://www.codexalimentarius.org/standards/list-of-standards/en/>

Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, The Codex Alimentraius Commission, (1999), CAC/GL 32-1999 <http://www.codexalimentarius.org/standards/list-of-standards/en/> Section1.5

Statutes of the Codex Alimentarius Commission (adopted in 1961 by FAO and in 1963 by WHO) <http://www.fao.org/DOCREP/005/Y2200E/Y2200E00.HTM>

Canada Statutes and Guidelines:

Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982 being Schedule B to the Canada Act 1982 (U.K.), 1982, c. 11. at s 2

Canada Food and Drugs Act, R.S.C. 1985, c.F-27, s 5 (1) and s 5.(2)

Consumer Packaging and Labelling Act, R.S.C., 1985, c. C-38,s 10

Food and Drug Regulations, C.R.C., c. 870 Division 28

Canada, Canadian General Standards Board , National Standard of Canada on Voluntary Labelling And Advertising of Foods That Are and Are Not Products of Genetic Engineering, (Canadian General Standards Board 2004), http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/norms-standards

Guidelines and Policies, Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms, Health Canada online, Health Canada <http://www.hc-sc.gc.ca/fn-an/gmf-agm/guidelines-lignesdirectrices/index-eng.php>

Guidelines for the Safety Assessment of Novel Foods Food Directorate Health Products and Food Branch, Health Canada, online: Health Canada<http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/gmf-agm/guidelines-lignesdirectrices-

eng.pdf>

European Union Treaties and Regulations:

Consolidated version of The Treaty Establishing the European Community, EU, 24 December 2002, OJ C325/35,< http://www.frontex.europa.eu>

Directive of the European Parliament and of The Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, OJC L 106/1, 17 Aril 2001

EC, European commission on the Regulation of GMOs in the EU /02/160 of July 2003, (2003) annex 5 at 1

Regulation (EC) Commission Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety,[2002] O.J.L.31/1, <http://eur-lex.europa.eu/LexUriServ> at Art 1(2)

Regulation EC Commission Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed [2003] OJ, L 268/1, at 13

Regulation EC Commission Regulation (EC) 1830/2003 of 22 September 2003 on Traceability and labelling of genetically modified organism [2003] OJ, L 268/24

Treaty of Amsterdam amending The Treaty of European Union, EU, 10 November 1997 <http://eur-lex.europa.eu/en/treaties/dat/11997D/htm/11997D.html>

England Statutes:

Genetically Modified Organisms (Traceability and Labelling) (England) Regulations, SI, 2004/2412

Genetically Modified Animal Feed (England) Regulations, SI, 2004/2334

Genetically Modified Food (England) Regulations, SI , 2004/2355

B. Case Law / Reports

World Trade Organisation- Dispute Settlement Board:

European Commission – Measures concerning meat and meat products (Hormones), (2009), WT/DS48/AB/R, (Appellate Board Report), online: WTO <http://www.wto.org>

European Commission- Trade Description of Sardines, (2002), WT/DS231/R, (Panel Report), online: WTO < http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds231_e.htm>

European Communities – Measures Affecting Asbestos and Asbestos- Containing Products, (2000), WT/DS135/AB/R, (Appellate Board Report),online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds135_e.htm>

European Communities — Measures Affecting the Approval and Marketing of Biotech Products,(2006), WT/DS291/R,WT/DS292/R,WT/DS293/R, (Panel Report), online: WTO <http://www.wto.org>

Japan – Measures Affecting Agricultural Products, (1999), WT/DS76/AB/R, (Appellate Board Report), online: WTO < http://www.wto.org>

Japan Taxes on Alcoholic beverages, (1996), WT/DS8/AB/R at para16 (Appellate Body Report) online: WTO <http://www.wto.org>

Japan-Taxes on Alcoholic beverages, 1996, WT/DS11/R, at 5.7, (Panel Report), online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds8_e.htm>

Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef, (2001), WT/DS161/AB/R and WT/DS169/AB/R (AB-2000-8), at paras 135–137 (Report of the Appellant Body), online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds161_e.htm>

European Court of Justice:

ECJ, Gowan Comércio Internacional e Serviços L v Ministero della Salute, C-77/09,[2009] EUR-Lex,<http://eur-lex.europa.eu/LexUriServ> at 16

ECJ, Karl Heinz Bablock and Others v Freistaat Bayern, C-442/09, [2011], EUR-Lex, <http://eur-ex.europa.eu/LexUriServ>

ECJ, Monsanto SAS v Ministre de l'Agriculture et de la Peche, Cases C-58/10 to C-68/10, [2010], EUR-Lex, < http://eur-lex.europa.eu/LexUriServ>

Canada:

Irwin Toy v. Quebec [1989] 1 S.C.R. 927

Codex Alimentarius Commission Committee Reports:

CCFL, 1st Sess, ALINORM 65/22 (1965), <http://www.codexalimentarius.org>

CCFL, 22nd Sess, ALINORM 93/22 (1993), <http://www.codexalimentarius.org>

CCFL, 23nd Sess, ALINORM 95/22 (1994), <http://www.codexalimentarius.org>

CCFL, 24th Sess, ALINORM 97/22 (1996), <http://www.codexalimentarius.org>

CCFL, 25th Sess, ALINORM 97/22A(1997),http://www.codexalimentarius.org

CCFL, 26th Sess, ALINORM 99/22 (1998), http://www.codexalimentarius.org

CCFL, 27th Sess, ALINORM 99/22A(1999), <http://www.codexalimentarius.org>

CCFL, 28th Sess, ALINORM 01/22 (2000),http://www.codexalimentarius.org

CCFL, 29th Sess, ALINORM 01/22A (2001),<http://www.codexalimentarius.org>

CCFL, 30th Sess, ALINORM 03/22 (2002), <http://www.codexalimentarius.org>

CCFL, 31th Sess, ALINORM 03/22A(2003), <http://www.codexalimentarius.org>

CCFL, 32nd Sess, ALINORM 04/27/22 (2004), <http://www.codexalimentarius.org>

CCFL, 33rd Sess, ALINORM 05/28/22 (2005), http://www.codexalimentarius.org

CCFL, 34th Sess, ALINORM 06/29/22 (2006), <http://www.codexalimentarius.org>

CCFL, 35th Sess, ALINORM 07/30 /22 (2007), <http://www.codexalimentarius.org

CCFL, 36th Sess, ALINORM 09/32/22 (2009), <http://www.codexalimentarius.org>

CCFL, 37th Sess, ALINORM 10/33/22 (2010), <http://www.codexalimentarius.org/committees-task-forces>

CCFL, 38th Sess, REP11/FL (2011), <http://www.codexalimentarius.org/committees-task-forces >

First session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (March 2000) WHO, online: <http://www.who.int/foodsafety/publications/biotech/ctf_march2000/en/index.html>

Report of the Facilitated Work Session of CCFL 39th session, (2011), CX/FL 11/39/13, <ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl39/fl39_13e.pdf>

C. Journal Articles/Websites

Albert Janice Lee, Labeling of genetically modified foods: Stakeholder perceptions of the food and drug administrations public consultation processes and food industry reactions to the United States voluntary and European Union mandatory policies, (Ph.D. diss., Tufts University Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy, 2007), [unpublished]

Anton Donald K. & Shelton Dinah L., "Problems in Environmental Protection and Human Rights: A Human Right to the Environment", online: (2011), ANU College of Law Research Paper No. 11-17, Social science research Network, http://papers.ssrn.com/sol3/papers.cfm

Bansal Sangeetha, Ramaswamy Bharat," Labels for GM foods; what can they do?", online: (2010) Economic and Political Weekly

Bracht Andersen L. "The EU Rules on Labelling of Genetically Modified Foods: Mission accomplished?", online: (2010),3 European Food and Feed Law Review, < http://www.citeulike.org/user/kwongchunlong/article/8061447> at 139

"Budget 2012" Government of Canada(29 March 2012), online: The Government of Canada <http://www.budget.gc.ca/2012/plan/chap5-eng.html>

Byrne P., "Labeling of Genetically Engineered Foods, online, Colorado State University Extension, <http://www.ext.colostate.edu>

"Canada's Biotechnology Strategy" Health Canada(2005 December 06), online: Health Canada < http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg>

Carter Collin A. & Gruer Guillaume .P., "International Approaches to the Labeling Genetically Modified Foods to Evaluate India's Proposed Rule", online: (2007), 10:1, AgBioForum, <http://www.agbioforum.org>

Caswell J.A., "Labelling Policy for GMOs:To each his own", online: (2000), 3:1, Agbioforum, < http://agbioforum.org/v3n1/v3n1a08-caswell.htm> at 55

Cijvat Ellie, Genetically modified organisms and the World Trade Organization, (M

Sc. Thesis, IIIEE Lund, Sweden, 2006) [unpublished]

Codex Alimentarius Codex Executive Committees, US Department of Agriculture Food and Inspection Service, http://www.fsis.usda.gov/codex_alimentarius/Codex_executive_committee/index.asp June 2012

Codex Committee on Food Labelling, United States Department of Agriculture Food safety and Information Services (2011), online: United States Department of Agriculture Food safety and Information Services <http://www.fsis.usda.gov/codex_alimentarius/Codex_Committee_Food_Labelling/index.asp>

"Codex Alimentarius and the Codex Commission", Ontario Ministry of Agriculture, Food and Rural Affairs, online: April 7, 2011 <http://www.omafra.gov.on.ca/english/food/inspection/codex.htm>

Commission of European Committees, Economic Impacts of Genetically Modified Crops on the Agri Food Sector, A first Review (2000)

Committee Detail of Codex Committee on Food Labelling, Codex Alimentarius Commission (2012), online: Codex Alimentarius Commission <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList=7>

Consumers International, News Release, "Consumer Rights Victory as US Ends Opposition to GM Labeling Guidelines", 5 July 2011, online: <http://www.consumersinternational.org/news-and-media>

Davison John, "GM plants: Science, politics and EC regulations" online:(2010), 178:2, Elsevier Plant Science, < www.elsevier.com/locate/plantsci,>

Depew Franklin M., "National and International Food Standards", online: (1964), 19, Food Drug Cosmetics Law Journal, <http://heinonline.org> at 492

Douglas Colette "Time that Goliath ate humble pie" The Daily Mail (London) (4 August 2000) online: The Daily Mail

Dr. Ewen W.B. Stanley & Pusztai Arpad, "Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine", online: (1999), 354:9187, The Lancet. <http://www.thelancet.com/journals/lancet/article/PIIS0140673698058607>

"Enzymes used in Food Processing", Health Canada, (16August 2010), online: Health Canada http://www.hc-sc.gc.ca/fn-an/securit/addit/food_enzymes-eng.php

European Commission Directorate General for Research, "The Europeans and Biotechnology 2010", (2010) < http://ec.europa.eu/public_opinion/archives>

"FAQ's-Purpose of Codex Alimentarius", online: Codex Alimentarius Commission, <http://www.codexalimentarius.net/web/faq_gen.jsp>

Fári, M.G. & Kralovánszky, U. P, "The founding father of biotechnology: Károly (Karl) Ereky", online: (2006), 12:1, International Journal of Horticultural Science < http://www.agroinform.com/files/aktualis/pdf> at 1

Federici Valery, "Genetically Modified Food And Informed Consumer Choice Comparing U.S. and E.U. Labeling law", online: (2010), 35, Brook. J. Int'l L.http://heinonline.org

Food and Agricultural Organisation, "FAO Statement on Biotechnology" (March 2000), online: The Food and Agricultural Organisation, <www.fao.org/biotech/fao-statement-on-biotechnology/en/>

Food Chain Evaluation Consortium Evaluation of the EU legislative framework in the field of GM food and feed ,Framework contract for evaluation, impact assessment and related services 12 July 2010, European Commission, DG SANCO, http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf at 129

Food Chain Evaluation Consortium, "Evaluation of the EU legislative framework in the field of GM food and feed", online: (2010), European Commission, < http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report> at 133

Food Safety, 20 Questions on Genetically Modified Food, WHO 2011, online: World Health Organisation <http://www.who.int/foodsafety/publications/biotech/20questions>

"Frequently asked questions – Biotechnology and genetically modified foods, Food and Nutirion", Health Canada,(19 June 2006) online: Health Canada< www. hc-sc.gc.ca>

Galloway Gloria, "U.S. drops objection to GM food labelling", The Globe and Mail, 6 July, 2011

Goldman Karen A, "Labeling of genetically modified foods: Legal and scientific issues", online: (2000), 12:3, Georgetown International Environmental Law Review

.http://heinonline.org

Gruere Guillaume P. and Rao S.R., "Review of International Labelling policies of genetically modified food to evaluate India's proposed rule", online: (2007), 10;1, Agbioforum <http://www.agbioforum.org/v10n1/v10n1a06-gruere.pdf> at 56

Gruère Guillaume P., "Labeling Policies of Genetically Modified food Lessons from an International Review of Existing Approaches", online: (2007), Brief No. 7, International Food Policy Research Institute https://www.cbd.int/doc/external/mop-04/ifpri-pbs-policy-07-en.pdf

Health Canada, Biotechnology, online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/biotech/index-eng.php>

Keane Steve, "Can a Consumer's Right to Know Survive the WTO?: The Case of Food Labeling", online: (2006-2007), 16, Transnat'l L. & Contemp. Probs < http://heinonline.org/ >

Kimbrell Eddie, "What is Codex Alimentarius?", online: (2000), 3:4, AgBioForum http://www.agbioforum.org/v3n4/v3n4a03-kimbrell.htm, at 197

Klintman Mikael, "Genetically Modified Food Labelling Controversy: Ideological and Epistemic Crossovers", online: (2002), 32:1, Social Studies of Science, Pg 76, http://www.jstor.org/stable/3182978

Krishna, P. & Perry, M.,"Making Sense of Mouse Tales: Canadian Lifeform Patents Topsy-Turvy" online: (2001), 23.4, European Intellectual Property Reviewhttp://westlawcanada.com

Kuiper H.A., Kleter G.A., Noteborn H.P., Kok E.J., "Assessment of the food safety issues related to genetically modified foods", The Plant Journal for cell and molecular biology.(online): 2001,27:6, http://www.ncbi.nlm.nih.gov/pubmed/11576435

"Labelling of Genetically Engineered Foods in Canada", Canadian Food inspection Agency, (10 May 2012), online: Canadian Food inspection Agency <http://www.inspection.gc.ca/food/labelling/other-requirements>

Legislative Council Secretariat, Genetically Modified Food Labelling by Diana Wong (Hong Kong: Research & Library Services Division 2003)

Lemaux Peggy G., "Genetically Engineered Plants and Food: A Scientist's Analysis of the Issues (Part1)", online, 2008, 59, Annual Review of Plant Biology, Sec. 2.3, http://www.annualreviews.org

Lucas Caroline, "The UK needs a labelling scheme for GM-free meat products", the

Guardian UK (10 February 2011), online: The Guardian <http://www.guardian.co.uk/environment/blog/2011/feb/10/labelling-gm-meat>

Lupien John R., "The Codex Alimentarius Commission: International Science Based standards, guidelines and recommendations" , online: (2000), 3:4, AgBioForum, <http://www.agbioforum.org/v3n4/v3n4a02-lupien.htm> at 194

MacDonald Chris & Whellams Melissa, "Corporate Decisions about Labelling Genetically Modified Foods", online: (2007), 75, Journal of Business Ethics, at 181, < http://www.jstor.org/stable/25123984>

Mackenzie Anne. A. "The Codex Alimentarius And Labeling Of GM Foods" online(2000)3:4,AgBioForum,<http://www.agbioforum.org/v3n4/v3n4a04-mackenzie.htm> at 205

Mansour Mark & Bennet Jennifer B., Codex Alimentarius, Biotechnoloogy and technical barriers to trade, online (2000),3:4, Agbioforum, <http://www.agbioforum.org/v3n4/v3n4a06-mansour.htm> at 213

Miller Henry I. & Kershen Drew L., "A label we don't need", Correspondence, Nature Biotechnology (8 November 2011) 971-972, < http://www.nature.com/nbt/journal>

Morgan David and Goh Gavin, "Genetically modified food labelling and the WTO agreement", online: 2004, 13: 3, RECIEL at 309.

"Paul Berg, Herbert W. Boyer, and Stanley N. Cohen", Chemical Heritage foundation, online, Chemical Heritage foundation <http://www.chemheritage.org/discover/online-resources/chemistry-in-history/themes/pharmaceuticals/preserving-health-with-biotechnology/berg-boyer-cohen.aspx>

Patterson, Lee Ann & Josling, Tim, "Regulating biotechnology: comparing EU and US approaches", online: (2002), European Policy Papers 8, Archive of European Integration. < http://aei.pitt.edu/28/>

Perry Mark, "Genetically Modified Organisms: Why we need transparent system of regulation", online: (2010), SSRN –id 1533657, Social Science Research Network < http://papers.ssrn.com/sol3/papers.cfm>

Phillips Peter W.B. & McNeill Heather, "A Survey of National Labelling Policies for GM Foods", online: (2000), 3:4, AgBioForum, < http://www.agbioforum.org>

Phillips Peter W.B. and McNeill Heather, "Labeling for GM foods: Theory and practice", online: (2000), 3:4, AgBioForum, http://www.agbioforum.org

Post Diahanna L. “The Precautionary Principle and Risk Assessment in International Food Safety: How the World Trade Organization Influences Standards’, online: (2006), 26;5, Risk Analysis http://onlinelibrary.wiley.com

Public Works and government Services Canada, “The 5 Percent Allowance in GE Food Labelling”, 19 Dec 2011,<http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/norms-standards/internet/032-0315/fiches-facts/fs01-eng.html>

“Public hostility to the genetic modification of crops risks slowing down the development of a potentially important technology—which is why more must be done to reassure consumers”, The Economist, (17 June 1999), online: The Economist, http://www.economist.com/node/213511

Runge C. F. & Jackson L. A., “Negative labeling of genetically modified organisms (GMOs): The Experience of rBST”, online: (2000). 3:1, AgBioForum, < http://agbioforum.org/v3n1/v3n1a09-runge.htm> at 62

“Safety Evaluation of Foods Derived from Modern Biotechnology” , OECD 1993, online: Organisation for Economic Cooperation and development, www.oecd.org/dataoecd/37/18/41036698.pdf

Sand Peter H., “Labelling Genetically Modified Food: The Right to Know” online: (2006), 15:2, Review of European Community and International Environmental Law, <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-9388.2006.00520.x/pdf at 189

Secretariat of the Joint FAO/WHO Food Standards Programme, “Understanding The Codex Alimentarius”, online: (2006), 3rd Ed, <ftp://ftp.fao.org/codex/publications/understanding/Understanding_EN.pdf> at 6

Sheldon Ian & Josling Tim, “Biotechnology Regulations and the WTO”, working paper 02-2, online: (2002), International Agricultural trade Research Consortium, <http:// www.iatrcweb.org> at 14

Shubber Sami, “The Codex Alimentarius Commission under International Law”, online: (1972), 21:4, The International and Comparative Law Quarterly < http://www.jstor.org/stable/758119> at 632

Somogyi Arpad, Hathcock John, Biesalski Konrad Hans, Blumberg B. Jeffrey, Antoine Michel- Jean, Edwards Gareth & Prock Peter, “Scientific issues related to Codex Alimentarius goals: A review of principles, with examples”, online; (2011), 60, Regulatory Toxicology and Pharmacology, <http://www.ncbi.nlm.nih.gov/pubmed/21382429> 161

“Sticky labels”, The Economist, (29 April 1999), online: The Economist, < http://www.economist.com/node/321496>

Summaries of EU legislation Consumer Information, online: Europa, , <http://www.frontex.europa.eu/assets/Legal_basis/12002E_EN.pdf>

Sunstein Cass R., "Beyond the Precautionary Principle" The Chicago Working Paper Series, online: (2003), Social Science Research Network, http://ssrn.com/abstract_id=307098

Teisl Mario F. and Caswell Julie A., "Information Policy and Genetically Modified Food: Weighing the Benefits and Costs", online (2003), Working Paper # 2003-1, University of Massachusetts Amherst-Department of Resource Economics, http://scholarworks.umass.edu/cgi/viewcontent.cgi?article=1195

The Regulation of Genetically Modified Foods, Health Canada, (28 Nov 2005),online: Health Canada < http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php>

USDA Foreign Agricultural Service, "Gain Report- Non-Biotech Labeling Rules in Place and Proposed Rules on Coexistence", online: (2012), FR9091, http://gain.fas.usda.gov at 2

Veeman Michele, "Labelling Policy for GM Foods: Pragmatism in Action or Policy Failure?", online: (2003), 4, Current Agriculture, Food & Resource Issues, <http://ageconsearch.umn.edu/bitstream/45733/2/veeman4-1%5b1%5d.pdf> at 109

Weirich Paul, ed, Labelling Genetically Modified food The Philosophical and Legal Debate, (Oxford, New York, USA: Oxford University Press, 2007)

Wildner Richard, "Codex Alimentarius Commission", online: (1973), 28, Food Drug Cosmetics Law Journal, <http://heinonline.org/HOL/LandingPage?collection=journals&handle=hein.journals/foodlj28> at 328

World Health Organisation, "General Information about Codex Alimentarius", 2012, <http://www.who.int/foodsafety/codex/general_info/en/index3.html>

Sowmya Vishwanatha

PROFESSIONAL EDUCATION

Graduate Studies

Western Law, Western University 2011- 2012
Thesis Title: The Codex: Labelling of Food derived from modern biotechnology
Thesis Advisor: Professor Mark Perry

Undergraduate Studies

Certificate of Qualification, National Committee on Accreditation (NCA), Ottawa 2008

Bachelor of Laws, Bangalore University Law College, India 1997
Bachelor of Academic Laws, Bangalore University Law College, India 1995
.

PROFESSIONAL QUALIFICATIONS

Called to the Bar in Ontario, Canada 2009
Called to the Bar in Karnataka (Bangalore), India 1999

GRADUATE RESEARCH EXPERIENCE 2011- 2012

Assisted in research on legislation concerning the regulation and labeling of transgenic crops.

PROFESSIONAL EXPERIENCE

Articled at Haney, Haney & Kendall (Waterloo) 2008 - 2009
Areas of experience include Corporate Law, Commercial Law, Real Estate and Wills.

Associate & Partner in Bangalore 1999 – 2005
Areas of experience include Intellectual Property Law, Corporate Law and Commercial Law.